# Missouri Medicine

The Journal of the Missouri State Medical Association www.msma.org/missouri-medicine November/December 2019


## EVALI Vaping Associated Lung Injury

### An Explosive United States Epidemic

**MSMA Advocacy & Legislative Forecast**
**Don't Be a Victim of Predatory Publishers**
**Marijuana, Mental Illness & Violence**
**Human Trafficking & Care Providers**
**Pickleball Injuries On and Off the Court**

# Give them focus.

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Helping students focus on their medical education for over 50 years, the Missouri State Medical Foundation has benefitted thousands of medical students statewide. We thank the many donors who have committed their energy and resources to fulfilling the Foundation's mission, and we are grateful for their generosity.

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The Foundation has also facilitated the creation of scholarship funds through a matching grant program. Our scholarship partners include:

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- Cole County Medical Society
- Kansas City Medical Society
- Northeast Missouri Medical Society
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- Saint Charles-Lincoln County Medical Society
- MSMA Alliance

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# Missouri Medicine

*The Journal of the Missouri State Medical Association - Since 1904*

Volume 116 | Number 6 | November/December 2019 www.msma.org/missouri-medicine




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www.msma.org/missouri-medicine





### About Missouri Medicine

In publication since 1904, the peer-reviewed, award-winning, bi-monthly *Missouri Medicine: The Journal of the Missouri State Medical Association,* is indexed by *Index Medicus*, MEDLINE, and PubMed. Complete issues archived at PubMed Central since 2010. Content appears on EBSCO Host Research databases.

With a large and respected editorial board and regular participation by Missouri's six medical schools on eight campuses, *Missouri Medicine* is among the nation's foremost state medical journals.

Articles are frequently cited in impact factor journals and regularly featured in the national media including: *Wall Street Journal, CSPAN-2, KevinMD, Outside Magazine, Runner's World, NBC News, General Surgery News, Ophthalmology Times,* and many others. Issues of *Missouri Medicine* are printed on acid-free paper with open access to digital issues available at www.msma.org/missouri-medicine-library.

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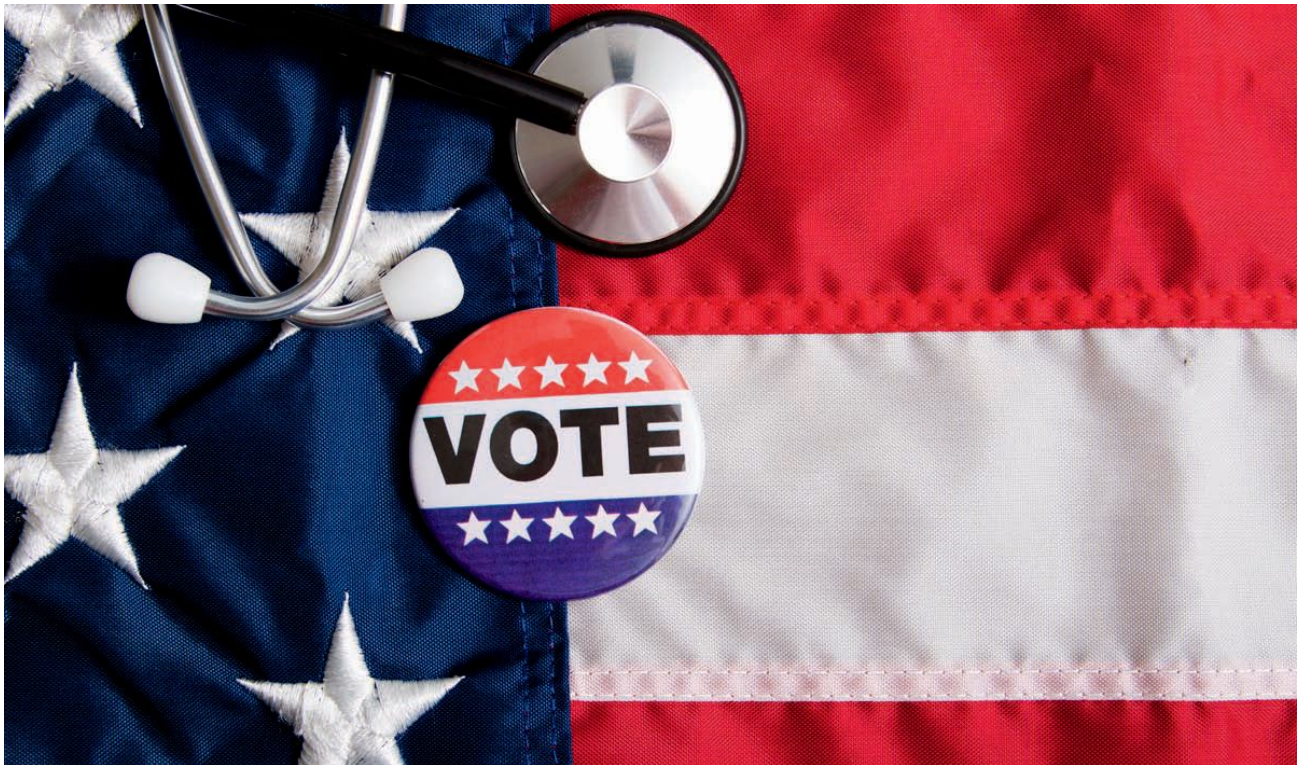
## *2020 National Elections Most Important Ever*



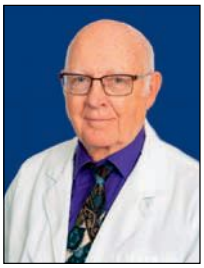

# A Year That Demands Your Attention & Participation

*by John C. Hagan, III, MD*

*"All animals are equal, but some animals are more equal than others."*
--Proclamation of the pigs, Animal Farm by George Orwell

All years are important. 2020 may be the most important election year ever! Ignore 2020 elections and legislative sessions at your personal and professional peril. Every legislative session proffers the consequences of good and bad law for physicians and their patients. This year we add the triple gravitas of local, state, and highly polarized national elections. With such epochal national issues as unaffordable 'Medicare for All', blatant socialism, and draconian taxation by candidate proxy on the ballot, physicians must have a say in national and state politics.

Individually we are an ineffectual and divided lot. Ever hear the one about the patient that consulted three different doctors and got five different opinions? In the Show-Me State of Missouri, the medical profession is fortunate to have the representation and advocacy of one of the top three medical associations in the United States. Since 1850, the Missouri State Medical Association (MSMA) has effectively championed the interests of Missourians and the physicians that provide their healthcare.



John C. Hagan, III, MD, FACS, FAAO, MSMA member since 1975, is a Kansas City, Missouri, ophthalmologist and *Missouri Medicine* Editor since 2000. He is a multi-year Diamond Contributor to MMPAC.
*Contact: jhagan@bizkc.rr.com*

**You need MSMA. MSMA needs you.**

MSMA accomplishments are extensive, and have been documented for decades in issues of Missouri Medicine. MSMA sponsored and enacted legislation that has benefited our patients, our medical profession, and our state. Recently think tort reform, raising evidentiary standards in medical malpractice cases, bolstering prudent layperson guidelines for emergency room visits and supported much needed prior-authorization reforms.

This is an important check-list of actions to take immediately:

- Renew your MSMA membership for 2020. If you are not a MSMA member, JOIN NOW! Contact Haley Wansing, MSMA Membership Director at 800-869-6762, or email hwansing@msma.org. MSMA dues are among the lowest in the nation and are a great investment, especially for young and mid-career physicians. MSMA represents all physicians: private practice, hospital-employed physicians, academic and physicians-in-training, and retired physicians. MSMA is the most effective advocate for funding for medical education & research.
- Help recruit a new MSMA member from your medical community. Membership recruitment and retention are the lifeblood of any organization. It all begins with engaged individual members and extends especially to MSMA leadership.
- Make a generous contribution to Missouri Medical Political Action Committee (MMPAC). Call 800-869-6762 with your credit card or send personal checks payable to: MMPAC, P.O. Box 1402, Jefferson City, MO 65102. If you have any questions, please contact MMPAC at 800-869-6762.
- Suggested amounts for practicing physicians are $250-$500, and $1,000 for MSMA Leadership (Officers/Council/MMPAC Board).
- Come to Jefferson City to serve as Physician of the Day and/or spend the day roaming the Capitol's halls advocating face-to-face with elected representatives and senators.
- Become active in the political campaigns of state and national candidates that will preserve the best of American medicine and culture while making it more affordable and available to the public.

You need MSMA. MSMA needs you. Together, we can keep the tort bar from rescinding tort reform, we can keep physician-wanna-be's from practicing medicine and surgery beyond their training and skills, and we can have you reimbursed fairly and promptly by third parties. Nationally, we can prevent the United States from following a catastrophic path into another impoverished socialist failed-state. **MM**

# MSMA: Combatting the Vaping Epidemic

*by James DiRenna, DO*

Happy Holidays! I bring you the warmest cheers from San Diego, California, after a productive and rewarding AMA Annual Meeting. I've just finished seeing patients, scanning emails, and paperwork on a Friday evening, but I want to send out a message to all how great and unified I felt with our group at the AMA in mid-November. The Heart of America Caucus and all other points of communication, collegiality, and camaraderie fell into place with the latest messages coming out of the AMA confirming it was a great meeting. The weather and attitudes of all were uplifting, and it seemed that all the positive emotions that I was experiencing brought great resolution and purpose to our activities and missions.

My interest for this column lies with our membership, with a heavy emphasis on scholarships for our students and residents and our anchor of advocacy. I was very fortunate to be invited to the Tennessee Medical Association annual conference in the first quarter of my presidency. Immediately I felt impressed by their passion and implemented strategies concerning their total state ban on "vaping."

Five resolutions were considered in the AMA's House of Delegates (HOD) relating to the cessation of vaping. In the resolution debate, the Tennessee language led the charge, and the HOD came to total agreement banning the new addiction of vaping. In Missouri, at present, the Governor has taken his position to have educational data brought together by the Department of Health and then submit this data to the House and Senate for the new legislative session in January 2020. MSMA will be following it next year.

My latest information on the vaping issue shows that U.S. Health Officials last week reported 2,290 confirmed cases and five more deaths from a mysterious repeating illness tied to vaping. The death toll is at 47 for the year (Reuters). The report goes on to state that vitamin acetate, which is believed to be used as a cutting agent in illicit vaping products containing marijuana components was found in lung samples from 29 patients who were tested. There also may be some association that pointed to vaping as containing THC, the psydioactive ingredient in marijuana.

James DiRenna, DO, 2019-2020 MSMA President and member since 1996, is from Kansas City, Mo., and practices Family Medicine for the Blessing Health System.
*Contact: james.direnna@mymlc.com*

MSMA represents allopathic and osteopathic physicians of every medical specialty. MSMA's advocacy team track hundreds of pieces of legislation each session for all the physicians in the state. These bills deal directly with patient care and matters pertaining to physicians' practice. However, I have realized over the years the most important attribute with the team is the close monitoring and observance of the addition and deletion of amendments to our legislation.

Over the last five years, MSMA has backed legislation that:

- Lowered physicians' insurance costs through tort reform (2015)
- Set standards of care in telehealth (2016)
- Raised evidentiary standards in medical malpractice cases (2017)
- Bolstered prudent layperson guidelines for emergency room visits (2018)
- Supported needed prior-authorization reforms (2019)

Our future emphasis will be addressing surprise medical bills, pushing for regulatory relief, enhancing access to care, and advocating for drug pricing transparency. These are just a few selected topics that MSMA will focus on for 2020.

We are constantly cultivating our medical society chapters, looking for more ways to get our residents involved. Nothing is more important than how we handle our membership. And nothing is more important than how we grow our students by supporting our scholarship programs.

In my term as president, it seems redundant to keep repeating the following reasons to be involved with MSMA, but I do it because it needs constant reinforcement to succeed. We all must realize the future of medicine is organized medicine. One must seek and develop the mindset that this is our profession—not a job. To the students and residents, MSMA moves medicine by influence, advocacy, practice management, eduction, professional networking, and time and money.

Peace, joy and hope to all! **MM**

# MSMA Legislative Preview 2020

*by Heidi Geisbuhler*

## *PDMP, Scope of Practice, Vaping, Anti-Vaccination...the List Goes On*

Missouri's 100th General Assembly will convene on January 8, 2020, to begin their second session of legislative work. The Capitol will be abuzz with activity until adjournment on May 15, 2020. In between those dates, your MSMA lobbyists will be tirelessly advocating for physicians and heading off attempts to interfere with your profession. Following is a list of some of the issues we expect to see during the first few months of 2020.

### Prescription Drug Monitoring Program

Missouri has been the only state without a statewide prescription drug monitoring program (PDMP) for several years, and it remains to be seen whether our status will finally change in 2020. Prior to 2019, legislation that would authorize a statewide PDMP faced opposition from a couple of devoted legislators. This past year, several more legislators joined the fight against a statewide PDMP, citing concerns about privacy and personal freedom. In the meantime, the St. Louis County PDMP gets rave reviews from many of our members and currently covers over 90% of the state's prescribers and patients. We look forward to working with Rep. Holly Rehder and Sen. Tony Luetkemeyer on this issue again next year.

### Vaping and Vapor Products

In October, Governor Parson called for the Departments of Health and Senior Services, Elementary and Secondary Education, and Public Safety to work together to create a statewide educational campaign to help make known the health risks of vapor products, especially among young people in Missouri. The governor also called on the legislature to work on restricting the sale of illicit vapor products, along with making it harder for minors to obtain vapor products. MSMA supports the governor and state agencies as they seek to decrease vapor product usage in Missouri, and we are eager to see vapor product-related legislation in 2020.

Heidi Geisbuhler is the Director of Legislative Affairs.
*Contact: heidi@msma.org*

### Anti-Vaccination

Throughout the legislative interim, your MSMA advocacy team joined an alliance of health care organizations, physicians, nurses, pharmacists, and concerned citizens called the Missouri Immunization Coalition to stay current on the anti-vaccination movement's activities around the country. The Coalition is comprised of a diverse group of stakeholders who know the value and public health benefits of vaccines and oppose anti-vaccination legislation.

Small but extremely vocal groups of vaccine-hesitant advocates have been active in California, New York, and almost every state in between during the legislative interim. Missouri, unfortunately, is not immune to anti-vaccination propaganda and has its share of grassroots advocates. Two anti-vaccination bills were proposed and defeated in the state legislature in 2019, but we expect to see more in 2020.

### Scope of Practice

In 2020, we expect to see familiar battles in the scope of practice realm. Advance Practice Registered Nurses (APRN) will likely push for independent practice and a license under the Board of Nursing (MSMA opposed both of these provisions in 2019). If independent practice proves impossible to achieve, APRNs will likely try to remove the geographic proximity requirements and expand their scope under the existing statute that governs collaborative practice arrangements instead.

MSMA will likely clash again with the physical therapists on the issue of direct access. In 2019, the

# Greet Your Physician Legislators

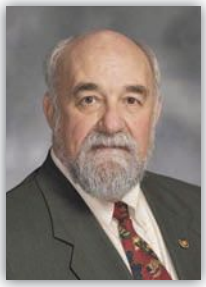
## Senator Bob Onder, MD (R)

**State Senate District 2 (St. Charles)**

**Hometown: Lake Saint Louis**

- Specialty: Allergy and Immunology
- MSMA Member since 1992
- Contact: bob.onder@senate.mo.gov

Serving his second term as Senator, Dr. Onder has been a tremendous friend to Missouri physicians throughout his tenure in the Senate. Dr. Onder served as the Senate Health Committee chair in 2019, a great place for an ally like him.



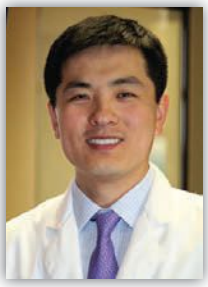
## Representative Jim Neely, DO (R)

**House District 8 (Cameron)**

**Hometown: Cameron**

- Specialty: Family Medicine
- MSMA Member since 2013
- Contact: jim.neely@house.mo.gov

Dr. Neely is serving his fourth term and has had a seat on the House Health and Professional Registration committees for several years. He's consistently been a friend to MSMA and we're excited to have him back for another term.



## Representative Jon Patterson, MD (R)

**House District 30 (Lee's Summit, Blue Springs, Independence, Unity Village)**

**Hometown: Lee's Summit**

- Specialty: General Surgery
- MSMA Member since 2011
- Contact: jon.patterson.md@gmail.com

Dr. Patterson, serving his first term, is a tireless physician advocate and MSMA is looking forward to working with him again on the MSMA agenda in 2020.

physical therapists wanted to treat patients for 10 visits or 21 business days before they had to consult a physician. Since current statute prohibits physical therapists from diagnosing, this proposal would have been irresponsible and, in some cases, dangerous for patients. MSMA fought that legislation last year and will continue to oppose it this year.

The assistant physicians may also return in 2020 with legislation that matches a 2019 bill that would have provided for an alternative pathway to licensure. The 2019 bill would have allowed an assistant physician who has practiced in a collaborative practice arrangement with a physician for five years to practice independently as a physician. MSMA opposed this bill because the assistant physician license was never intended to be an alternative to a medical residency program. It was intended to be a bridge between medical school and residency and a way for medical students who didn't match with a residency program to gain valuable and meaningful experience working in collaboration with a licensed physician.

### Credentialing Reform

In 2019, many physicians and hospital systems expressed their frustration with the medical credentialing process. We've heard many stories of credentialing-related disruptions and delays in reimbursement for our members. MSMA plans to work with the Missouri Hospital Association and other healthcare groups in 2020 to support legislation to make the credentialing process smoother and less of a headache for everyone involved.

### Tort Reform

Punitive damages legislation unfortunately was sidelined last year, as only a handful of tort reform bills made it


through the legislature. 2019's bill would have raised the burden of proof for punitive damages so that statutory law would match case law. We look forward to working with Sen. Bill White on this topic in 2020.

### Tanning Bed Prohibition

MSMA has testified in favor of legislation that would ban tanning bed use by anyone under 18 years old for the past several years, and we plan to do so again in 2020. The legislation would also require trained staff members to be present at tanning facilities at all times. In 2019, we joined cancer survivors, families of those affected by skin cancer, dermatologists, pediatricians, and many others to support this legislation.

### Medical Marijuana

As medical marijuana dispensaries, cultivation facilities, and processing facilities officially begin operation in 2020, we'll be keeping an eye on legislation and department rules that could change how these facilities are regulated or the way the state administers the medical marijuana licensing program for patients.

### Doctor of the Day

Come spend a day advocating for your profession and your patients in Jefferson City! Every year from January to mid-May, MSMA members from all over the state volunteer their time and services for a day at the Capitol during the legislative session. During your visit, you'll get to visit with your local elected officials, see the Senate and House chambers, assist legislators and their staff with minor medical ailments, and check in with MSMA's lobbying team. It's a great way to become more familiar with the Capitol and get more involved in physician advocacy. Sign up today at msma.org/physician-of-the-day or contact Heidi Geisbuhler at heidi@msma.org for more information. All specialties are welcome and encouraged to volunteer!

### White Coat Day 2020

The MSMA White Coat Day is scheduled for Tuesday, March 3, 2020. This advocacy event is a great opportunity to visit the Missouri State Capitol in Jefferson City to advocate on behalf of physicians and patients. Legislators will deliver brief remarks on health care legislation from 9:00-10:00 AM in the first floor rotunda of the Capitol. At noon, MSMA will provide lunch for attendees.

Throughout the rest of the day, we encourage physicians to meet with their local legislators, explore the building, and network with fellow MSMA members. There may be additional meetings and presentations participants wish to attend, as some state medical specialty societies are planning to join the rally that day. All physicians and medical students are welcome to take part, even if you can only visit the Capitol for an hour or two! RSVP today at www.msma.org/white-coat-day.

### Contact Us!

If you have any questions about MSMA's work in the Capitol or would like more information about a particular legislative issue, please don't hesitate to contact Jeff Howell at jhowell@msma.org or Heidi Geisbuhler at heidi@msma.org. **MM**


## POLICY

***What is MSMA's policy regarding medical marijuana?***

MSMA adopted the following policy regarding medical marijuana in 2017:

"MSMA believes there is evidence that suggests marijuana and its related derivatives may have therapeutic benefits for patients with certain medical conditions. As such, MSMA calls on the Food and Drug Administration and the Drug Enforcement Administration to promptly revise marijuana's current classification as a Schedule I controlled substance in order to facilitate evidence-based, scientifically-valid clinical research to evaluate its efficacy and safety."

***What is AMA's policy regarding medical marijuana?***

The AMA has a number of existing policy positions on marijuana.

Policy on cannabis and cannabinoid research can be found here.[1]

Policy on medical marijuana can be found here.[2]

Policy on recreational marijuana use can be found here.[3]

***Where can I find the Missouri medical marijuana amendment and the rules promulgated by the Department of Health and Senior Services?***

The medical marijuana amendment (Amendment 2 from 2018) can be found at the Secretary of State's website here.[4] An overview of the Department's rules regarding medical marijuana can be found on the DHSS website here.[5] The rules in their entirety can be found on the Secretary of State's website here[6] and here.[7]

## PHYSICIANS

***Are physicians required to complete the physician certification form?***

No. There is no requirement to complete the physician certification form if a physician does not agree that the patient has a qualifying condition or does not believe medical marijuana to be an appropriate treatment for the patient, or does not believe medical marijuana to be an appropriate treatment for any patient.

***Where can I find a physician certification form?***

The physician certification form can be found on the Department of Health and Senior Services website here.[8]

***What specifications must a physician meet before they are allowed to complete a physician certification for a patient?***

A physician who completes a physician certification form must be an active Missouri-licensed MD or DO in good standing with the Board of Registration for the Healing Arts.

## *Medical Marijuana Frequently Asked Questions*

***Can any other medical provider complete a physician certification?***

No. Only a Missouri-licensed allopathic (MD) or osteopathic (DO) physician in good standing may complete the physician certification.

***What must physicians do prior to certifying a patient with a qualifying condition?***

A physician who wishes to certify a patient with a qualifying condition must be a licensed Missouri physician in good standing with the Board of Registration for the Healing Arts.

Prior to completing the physician certification form, a physician must meet with and examine the qualifying patient, review the patient's medical records or medical history, review the patient's current medications and allergies to medications, discuss the patient's current symptoms, and create a medical record for the patient regarding the meeting. A physician must also discuss risks associated with medical marijuana with the patient, including known contraindications applicable to the patient, risks of medical marijuana use to fetuses, and risks of medical marijuana use to breastfeeding infants.

Once this is completed, and a physician concludes that the patient suffers from a qualifying condition and medical marijuana is an appropriate course of treatment, the physician then may complete the certification form.

***Must a physician-patient relationship be established before certifying a patient?***

Yes. Establishing a physician-patient relationship under Missouri state law includes an in-person physical examination, medical interview, and a review of a patient's medical records prior to completing the physician certification form.

***What constitutes a complete medical record for a patient seeking a physician certification form?***

Missouri requires physicians to complete an adequate and complete medical record for each patient, including patients for whom a medical marijuana certification is completed. Under state law, An adequate and complete patient record shall include documentation of the following information:

(1) Identification of the patient, including name, birthdate, address and telephone number;
(2) The date or dates the patient was seen;
(3) The current status of the patient, including the reason for the visit;
(4) Observation of pertinent physical findings;
(5) Assessment and clinical impression of diagnosis;
(6) Plan for care and treatment, or additional consultations or diagnostic testing, if necessary. If treatment includes medication, the physician shall include in the patient record the medication and dosage of any medication prescribed, dispensed or administered;
(7) Any informed consent for office procedures.

Records must be made available to the Missouri Board of Healing Arts upon request, and must be maintained by the physician for a minimum of seven years from the last time the patient was seen.

### PATIENTS & PROCEDURE

***How does a patient obtain a license to use medical marijuana?***

A patient must visit an active Missouri-licensed MD or DO in good standing with the Board of Registration for the Healing Arts and request that the physician complete a physician certification form. The physician certification form is not a recommendation that the patient should use medical marijuana - it simply verifies that the physician believes the patient has a qualifying condition. The patient must then submit the form to the Department of Health and Senior Services with an application and application fee.

Once the DHSS online submission system becomes available, the physician must submit the physician certification form directly to the department. Until the system is online, patients should submit their physician certification form with their application and application fee.

## *Medical Marijuana Frequently Asked Questions*

***What conditions qualify for a patient to receive a medical marijuana license?***

- Cancer
- Epilepsy
- Glaucoma
- Intractable migraines unresponsive to other treatment
- A chronic medical condition that causes severe, persistent pain or persistent muscle spasms, including but not limited to those associated with multiple sclerosis, seizures, Parkinson's disease, and Tourette's syndrome
- Debilitating psychiatric disorders, including, but not limited to, post-traumatic stress disorder, if diagnosed by a state licensed psychiatrist
- Human immunodeficiency virus or acquired immune deficiency syndrome
- A chronic medical condition that is normally treated with a prescription medication that could lead to physical or psychological dependence, when a physician determines that medical use of marijuana could be effective in treating that condition and would serve as a safer alternative to the prescription medication
- A terminal illness
- In the professional judgment of a physician, any other chronic, debilitating or other medical condition, including, but not limited to, hepatitis C, amyotrophic lateral sclerosis, inflammatory bowel disease, Crohn's disease, Huntington's disease, autism, neuropathies, sickle cell anemia, agitation of Alzheimer's disease, cachexia, and wasting syndrome

***How long before a certified patient license expires?***

A patient identification card expires one year after the card is issued by the department.

***How long does the state retain information on certified patients?***

Patients must reapply every year for a patient identification card. DHSS has not adopted policy regarding how long patient information is retained.

***If a patient already has a medical marijuana license from another state, are they automatically eligible for a patient license in Missouri?***

No. A patient must have a Missouri medical marijuana license to use and purchase medical marijuana in Missouri. There is no reciprocity with other states.

***Can patients use medical marijuana in the hospital?***
***Can a physician certify hospital-based patients?***

Marijuana is listed as a schedule I drug by the DEA and FDA, which are defined as drugs with no currently accepted medical use and a high potential for abuse. As such, many hospitals in Missouri face legal uncertainties when considering the effects of allowing medical marijuana on their premises. A handful of hospital systems have already adopted policies that prohibit medical marijuana on their premises and prohibit the physicians their system employs from certifying patients.

Hospitals and other health care facilities in Missouri are subject to federal law if they receive reimbursement from federal programs like Medicare and Medicaid. These hospitals in particular may be hesitant to jeopardize their reimbursement eligibility status by allowing patients to possess Schedule I drugs in their facilities.

Certification forms for hospital-based patients will have to be considered on a case-by-case basis, depending on the hospital's policies and regulations. The Missouri Hospital Association has issued some guidance on hospital-specific medical marijuana topics. It can be found at their website.[9]

***How does a physician know what the proper dosage is for a patient?***

The dose authorized by the physician certification form per 30-day period is four ounces of dried, unprocessed marijuana or the equivalent. If a patient wishes to purchase more than that amount per 30-day period, the patient must present certification and an alternate recommended dose from two physicians.

## *Medical Marijuana Frequently Asked Questions*

***Is there a way to restrict a certified patient from using smokable marijuana?***

No. A physician certification form is not a recommendation or a prescription. The physician only certifies that a patient has a qualifying condition. The method in which the patient consumes marijuana is up to the patient's preference.

***Is it okay to certify a child with a qualifying condition?***

If a physician wishes to certify an unemancipated minor under 18 with a qualifying condition, the physician must receive the written consent of a parent or legal guardian who asserts that he or she will serve as a primary caregiver for the qualifying patient.

***When does a physician certification expire?***

A physician certification expires 30 days after the completion of the physician certification form.

***Does the Department of Health and Senior Services keep a list of physicians who will complete a physician certification?***

No. At this time, DHSS does not maintain such a list.

### DISPENSARY/CULTIVATION FACILITIES

***When will a patient be able to purchase medical marijuana from a licensed facility in Missouri?***

The Department of Senior Services estimates that licensed medical marijuana facilities will be operational by January 2020.

***Are there any education and training requirements for employees of a licensed dispensary or licensed cultivation facility?***

Yes. Facility employees and facility security managers must complete security training related to theft-prevention and controlled access areas, training related to the methods of cultivation, processing, or testing used by the facility, training related to sanitation procedures, training related to the differences in the purported effects and effectiveness of the strains of medical marijuana available for purchase at that dispensary and the methods of their use, training related to recognizing the signs of medical marijuana abuse, and training related to HIPAA requirements and the DHSS-operated statewide track and trace system. If licensed to operate by DHSS, a dispensary or cultivation facility must adhere to department regulations and standards.

***If they possess a medical marijuana license, can a patient cultivate their own medical marijuana?***

If a patient who is approved for a medical marijuana card also applies for a patient cultivation identification card, they may cultivate up to six flowering plants per patient. The patient must also abide by security protocols from DHSS if they wish to cultivate their own plants.

### RESOURCES & LINKS

**1. https://policysearch.ama-assn.org/policyfinder/detail/Cannabis?uri=%2FAMADoc%2FHOD.xml-0-5331.xml**
**2. https://policysearch.ama-assn.org/policyfinder/detail/Cannabis?uri=%2FAMADoc%2Fdirectives.xml-D-95.969.xml**
**3. https://policysearch.ama-assn.org/policyfinder/detail/Cannabis?uri=%2FAMADoc%2FHOD.xml-H-95.924.xml**
**4. https://www.sos.mo.gov/CMSImages/Elections/Petitions/2018-051.pdf**
**5. https://health.mo.gov/safety/medical-marijuana/rules.php**
**6. https://health.mo.gov/safety/medical-marijuana/pdf/emergency-rules-sos.pdf**
**7. https://www.sos.mo.gov/CMSImages/AdRules/csr/current/19csr/19c30-95.pdf**
**8. https://health.mo.gov/safety/medical-marijuana/pdf/physician-certification-form.pdf**
**9. https://web.mhanet.com/medical-marijuana.aspx**

**More resources at www.msma.org/medical-marijuana**
**Contact MSMA at 800-869-6762 or email heidi@msma.org.**

MISSOURI MEDICAL Political Action Committee
www.msma.org/mmpac

# MMPAC: Thank You for Your Support in 2019-2020

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# Physician Advocacy: The AMA Interim Meeting 2019

*by the Missouri Delegation to the AMA and compiled by Charles Van Way, III, MD*

The Interim Meeting of the American Medical Association (AMA) House of Delegates (HOD) in San Diego, California, November 15-16, was focused on legislation and public advocacy. The purpose of a meeting halfway between the annual June meetings is to allow the organization to respond quickly to time-sensitive issues. The scope of resolutions is reduced, and there are only five reference committees. But there is no shortage of important issues. Issues highlighted on the AMA website include the opioid epidemic, vaping, access to health care, drug pricing, and Medicaid reform. We usually have the meeting somewhere else than Chicago, and since it's late in the year, somewhere warm. Which is admittedly a fringe benefit.

Patrice Harris, MD, the President of the AMA, spoke of trust. Trust, she said, is scarce today, yet people still trust their physicians. This is rooted in three characteristics: competence, honesty, and compassion. Physicians know their jobs. Few professions carry out such relentless self-examination. We are honest, calling out invalid and unscientific fads and publicity. We are compassionate, fighting for health equity. Compassion leads us to advocate for humane treatment and health care for immigrants at our country's borders. Because it hurts patients, the AMA opposes "surprise billing". We want to reform electronic health records (EHR), and to empower technology to improve health care.

James Madara, MD, Executive Vice President, began by citing Elon Musk, who commented that "Excessive automation at Tesla was a mistake. Humans are under-rated." Optimum technology must be blended with human effort. The AMA is working to improve the care of chronic disease by improved technology. To improve the care of hypertension, technology will allow patients to measure blood pressure at home and have the values transmitted directly to the patient's medical record. A joint effort with the American College of Cardiology aims to include 22 million hypertensive patients. In other initiatives, the AMA is working to improve continuing medical education and to reconfigure undergraduate medical education.

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Since 2003, there has been a public member to the Board of Trustees (BOT). In 2020, that will be Harris Pastides, PhD, the retiring president of the University of South Carolina. Besides having a stellar record at USC, he has been a strong leader in civil rights and equal opportunity. In his acceptance speech, he said that he wants to help the AMA lead the reform of American health care. A "first college graduate" in his immigrant family, he is especially concerned about maintaining access to medical education for all. He feels strongly that no student should be turned away because they cannot afford medical education.

For the past four years, the Council on Ethical and Judicial Affairs has been working to craft an acceptable statement of the ethics of maintaining competence in the face of advancing age. It mandates we evaluate our own competence as we progress through the stages of life. All of us need to be concerned, with self-assessment and self-awareness. And not only for ourselves, but for our colleagues. The current policy can be seen at the AMA website.[1,2]

The HOD continues to address the high cost of drugs. A Council report and several resolutions proposed such innovations as competitive bidding, international price indices, increased transparency, and mandatory arbitration. Resolutions called for inclusion of co-pay coupons in health plan deductibles and for Sunshine Act disclosures by pharmacists and pharmacy benefit managers. There was a general agreement that this is an issue which needs continued attention, and which will require a multi-faceted approach. Separate but related resolutions advocated identification of the country of origin of all pharmaceuticals.

A resolution was passed to strengthen AMA advocacy for a pass/fail grading system in medical schools. Another resolution reaffirmed AMA policy to lessen the financial and time impact of Step 2 CS examination on medical students. There were resolutions to enhance medical education in

The Missouri Delegate to the American Medical Association Interim Meeting in San Diego, California, November 15-16, 2020.

the areas of nutrition and in LBGTQ care. A resolution called for IRB training in research protections for LBGTQ individuals. One resolution advocated better treatment of health care coverage for medical students, to include such clinically-related injuries as needle sticks and diseases. A resolution wished to address problems in the National Resident Matching Program (NRMP), and the shortfall of residency program positions. The number of U.S. graduates who are unable to obtain training positions through the match continues to grow. Another resolution called for the Veterans Administration to provide more training positions. These issues will be considered in detail by the BOT.

There was a report from the Council on Medical Education and a separate resolution, both of which called for increased instruction on healthcare finance for students and residents. This originated in a resolution from Missouri, adopted at the 2018 annual meeting, resulting in the Council report. It's always good to see an issue from Missouri which has been carried forward into AMA policy.

In July 2019, Hahnemann Hospital of Philadelphia declared bankruptcy, leaving 571 residents and fellows in limbo. Along with other disruptions, their malpractice tail coverage was stopped. This, according to state law, jeopardized their continuing medical licensure. The BOT will consider ways and means to help these unfortunate trainees, as well as to work with the ACGME and CMS to try to ensure such a training catastrophe cannot happen again.

The AMA has, for the past three years, held "Camp AMA", which provides child care at the AMA meetings. Strongly supported by the Young Physicians' Section (YPS) and the Medical Students Section (MSS), a resolution called for this to be continued as a permanent part of the AMA meetings, and to be free to participants. This will greatly encourage participation by younger physicians and medical students, something which has been a goal of the AMA for the last decade. Both state sections meet at the MSMA annual meeting, and national sections at both AMA meetings each year.

The YPS has been particularly concerned about the treatment of immigrants at the border. Joining with Dr. Harris, the YPS will continue to work for improvements in health care in the detention centers. A resolution opposed the mandatory collection of DNA samples from undocumented immigrants. Another asked the AMA to advocate for state legislative bans of "conversion" therapy for sexual orientation or gender identity. Another resolution asked for a ban on child marriage, leaving the definition of 'child' to state legislatures.

There were two BOT reports dealing with the opioid crisis. The AMA has called for increased ability for primary care practices to dispense methadone, for creation of Quick Response Teams, and for strengthening of local strategies to address the crisis. In a related issue, a resolution called for national prescribing guidelines for benzodiazepines. This was discussed at some length in reference committee, with little consensus. Some feel opioid guidelines put out by the Centers for Disease Control (CDC) have been a success, while others say they have not been helpful. This issue was

basically deferred, but will be brought up again later. A major question is, who will write the guidelines? The CDC has little expertise in psychiatric medications, and the FDA has shown little enthusiasm for writing practice guidelines.

There were several resolutions on cannabis use. A report from the Council on Science and Public Health outlined the complex legal and medical issues. It was strengthened to recommend that hospitals should not allow the use of cannabis within the facility. As this is a recommendation only, hospitals and medical staffs are free to do whatever they wish, but if they wish to ban cannabis, the AMA is supportive. Additionally, the HOD has now called for increased research on the effect of cannabis legalization, greater engagement with the public health system, outreach to the public, and formation of a Cannabis Task Force to engage the public and physicians. There was extensive discussion of state-level initiatives both for medical use and for full legalization. The AMA continues to maintain opposition to so-called "medical" marijuana and to full legalization.

Resolutions dealt with other specialized issues. A resolution called for the AMA to evaluate school resource officers. Two resolutions advocated for the protection of health data under net neutrality, regardless of how that particular debate plays out. A resolution called for action to end the racial pay gap among physicians. A resolution supported extension of DALCA, the legalization of children of immigrants on valid visas. Many such immigrants are physicians.

There was considerable discussion of forced organ harvesting, which is said to be continuing in China. The HOD has asked the AMA to study this issue. The issue has been considered by the World Medical Association, and the practice is against the law in China. But recent studies have documented the continuation of the practice.[2,3]

The use of Electronic Nicotine Delivery Systems (ENDS), otherwise known as "vaping," continues to be of significant concern. There were several resolutions which called for regulation, bans on flavoring, and total bans. The outcome was that the HOD would like to see a ban on vaping at least until the FDA has produced regulations and will continue to support a ban on the use and sale of ENDS to minors.

MIPS (Medicare Incentive Payment System) continues to be non-functional. The system is flawed and has not shown any positive results. A BOT report on MIPS was considered too weak and was sent back for a re-do. While there is existing AMA policy calling for improvement in MIPS, the sense of the House was that the AMA should actively work to have CMS abandon MIPS.

The House passed resolutions to support the use of "veterans' courts" which have expertise in the treatment of veterans with PTSD and other psychiatric disorders. A different resolution supported the use of "drug courts", which are specifically constituted to deal with drug-addicted offenders. Both types of courts can divert appropriate individuals from the prison system to treatment facilities. Both have proven effective.

The meeting of the Organization of State Medical Association Presidents (OSMAP) was, as usual, the day before the meeting. Dr. Harris, spoke of the current directions of the AMA, especially the importance of health equity. Gary Price, MD, president of the Physicians' Foundation, spoke of their work on defining socioeconomic determinants of health, and on their forthcoming physician survey. The Foundation does such a survey every two years, and this year's survey will inform AMA policy in the 2020 election year. "Surprise medical billing" has been the subject of legislation in New York and California and pending Federal legislation. It was discussed at length. Surprise billing is basically an artifact of the increasing use of narrow networks by insurance companies. Legislation in California allowed insurers to pay at or slightly above Medicare rates, while legislation in New York mandates payment at more realistic charges, with an arbitration mechanism. While both of these would address the problem from a patient's standpoint, the California approach cuts physician reimbursement, and has adversely affected access to specialty care in California. The New York approach has cut surprise billing by a third, and has saved patients $400 million in emergency care.

Missouri physicians continue in leadership roles. David Barbe, MD, is now President-Elect of the World Medical Association, representing the AMA in that organization. Edmond Cabbabe, MD, serves on the Council for Long Range Planning and Development. David Fleming, MD, serves on the Council on Ethical and Judicial Affairs. Charles Van Way, MD, continues to serve on the Steering Committee of OSMAP.

All of the reports and resolutions adopted in the meeting are available on the AMA website. Highlights from the meeting are at https://www.ama-assn.org/house-delegates/annual-meeting/highlights-2019-ama-interim-meeting.

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MM

# Residents and Fellows Moving Medicine at AMA Interim 2019

*by Joanne Loethen, MD*

Joanne Loethen, MD, far left, Resident and Fellow Section, discusses resolutions at one of the Missouri caucuses.

The AMA's Resident and Fellow Section (RFS) met November 15-16 for the 43rd gathering of the section as part of the Interim AMA Meeting in San Diego. Over 160 residents and fellows of nearly every specialty came together to address issues pertaining to medical trainees. As part of this meeting, the RFS heard from Patrice Harris, MD, current AMA president, who spoke to how the AMA is working to enhance engagement among early-career physicians—a group who brings an important perspective to healthcare. Erin Sutton, JD, of the AMA Litigation Center talked to the partnership between the AMA and state medical associations and how the AMA provides legal support when a given legal case pertains to AMA policy. This partnership illustrates the importance of each AMA meeting where such policy is shaped, thereby giving the AMA policy to stand on when speaking on behalf of physicians.

Todd Askew, AMA's Senior Vice President of Advocacy, updated the RFS on ongoing advocacy efforts of the AMA including the continued excess of uninsured and underinsured patients in the U.S. Though the Affordable Care Act has dramatically improved the uninsured rate, there is still work to do. Among those uninsured in America, half are eligible for insurance through the exchanges but do not realize it and therefore unnecessarily continue without insurance.

Grayson Armstrong, MD, RFS member of the AMA Board of Trustees, expanded on the Reimagining Residency Initiative and how training programs across the country are breaking from the often outdated mechanisms of medical training - re-thinking how medical trainees prepare for their careers. Dr. Armstrong also expanded on AMA's Integrated Health Model Initiative, a health care collaboration to improve patient outcomes by empowering physicians with the clinically valid health care data to make informed clinical decisions.

From a policy standpoint, the RFS asked the AMA to help address protections for and better processes by which medical trainees can continue training in the event of hospital or training program closure. This ask was in light of the recent Hahneman University Hospital closure that left 571 residents and fellows without a position for ongoing training. Other policy issues pertaining to residents and fellows included:

- Advocating for minimum standards of parental leave for trainees. Residents and fellows should be ensured adequate time off while maintaining the ability to complete training on time;
- Encouraging evidence-based practices to address trainee burnout prevention and mitigation; and,
- Creating new ICD-10 codes for vaping-related lung injury so that these cases can be better tracked on a systemic level.

At the meeting, Missouri's residents and fellows were represented by Anup Bhattacharya, MD, (WUSTL, Rad), Frances Mei Hardin, MD, (MU, ENT), Jared Lammert, MD, (MU, EM), and Joanne Loethen, MD, (UMKC, Med-Peds). For more information about the RFS, visit www.msma.org/resident-fellow-section. **MM**

# MSMA Young Physician Leaders: Addressing Vulnerable Populations

*by Marc Mendelsohn, MD, Laurin Council, MD, Rachel Kyllo, MD & Albert Hsu, MD*

The Young Physicians Section (YPS) of the AMA includes any physicians who are under 40 years of age or within their first eight years of practice (after residency or fellowship training). At the AMA Interim Meeting in San Diego, California, the AMA YPS adopted two resolutions for consideration by the House of Delegates (HOD) next June: (a) encouraging wider availability of altruistic cord blood donations, and (b) encouraging TRICARE to cover fertility preservation procedures for medical indications, and also to cover gamete preservation prior to deployment, for active-duty military personnel.

Missouri's Nathan Nolan, MD, served as the Alternate Delegate to the American College of Physicians and on AMA's Reference Committee C.

AMA YPS also brought a resolution to the HOD, regarding childcare services at AMA meetings. This resolution was passed by AMA HOD with broad support, ensuring that "Camp AMA" will continue to provide childcare at AMA meetings, and at no cost to members. This will enhance the accessibility of future national meetings to all AMA members with young children, including many students, residents, and young physicians.

The HOD also adopted policy to encourage establishment of a two-interval (pass/fail) grading for non-clinical curriculum in U.S. medical schools. Such a system is currently in effect in most (>70%) U.S. medical schools today; this will help standardize medical education and positively impact the emotional and physical health of students across the nation. Our AMA also established a Cannabis Task Force to analyze emerging research and give guidance to organized medicine, especially regarding vulnerable populations (pregnant women, children, certain psychiatric patients) who probably should not be using cannabis, regardless of local and state laws.

Drs. Patrice Harris, Scott Allen, and Sarah Goza spoke about the family detention centers along the southern US border. Dr. Allen is famous for being one of two government-employed physicians who have become whistle-blowers regarding appalling and ghastly conditions at the border. Their insights, stories, and first-hand artwork brought the horrors of this situation into stark focus for attendees, further highlighting the importance of physician advocacy for vulnerable populations.

Additional topics discussed during the meeting, of interest to YPS members, included:

- Physician health policy opportunities
- public health impacts and unintended consequences of legalization and decriminalization of cannabis
- Addressing the racial pay gap in medicine
- Improving emergency response planning for infectious disease outbreaks
- Ending child marriage
- Benzodiazepine-specific prescribing guidelines for physicians
- Veterans Health Administration funding of graduate medical education
- Banning conversion therapy of LGBTQ youth
- Endorsing the creation of a Lesbian, Gay, Bisexual, Transgender, and Queer (LGBTQ) Research IRB training
- Legalization of the deferred action for legal childhood arrival (DALCA)
- Improving inclusiveness of transgender patients

The AMA YPS representatives are Marc Mendelsohn, MD, American College of Emergency Physicians alternate delegate to AMA HOD, St. Louis; M. Laurin Council, MD, American Society for Dermatologic Surgery alternate delegate to AMA HOD; St. Louis; Rachel Kyllo, MD, Delegate to AMA YPS; St. Louis; and Albert Hsu, MD, Immediate Past Chair of MSMA YPS, MSMA Delegate to AMA YPS; Columbia.

For more information about YPS, visit www.msma.org/young-physicians-section. **MM**

# Can Your Medical Opinion Subject You to Criminal or Civil Liability?

## *Recent Federal Cases Involving Medical Opinions and False Claims*

*by Emily Park, JD*

When providing health care services that are reimbursed by federal health care programs (i.e., Medicare and Medicaid), or other third party payers, providers must comply with a number of health care fraud and abuse laws, including the False Claims Act and a number of criminal statutes, including a statute specifically addressing healthcare fraud. The False Claims Act (FCA) imposes civil liability on those who present, or cause to be presented, a false or fraudulent claim for payment to the federal government.[1] While the FCA imposes civil liability, there are separate criminal statutes that can be used by the government to prosecute false claims and healthcare fraud.[2]

Beginning in the early part of this decade, both the government and *qui tam* relators began scrutinizing hospices, which has created a unique body of law concerning the intersection of subjective clinical judgments and the objective falsity required in civil and criminal false claim cases.[3]

Coverage for hospice services was added to the Medicare program in 1985. For patients covered by Medicare to be eligible for the hospice benefit, the patient must elect to forego all curative treatment for the terminal illness and must obtain a certification from two physicians that he or she has a prognosis of a life expectancy of six months or less if the illness runs its normal course.[4] Only allopathic and osteopathic physicians can certify or re-certify that a patient has a life expectancy of six months or less.[5]

Section §1814(a)(7) of the Social Security Act specifies that certification of terminal illness for the hospice benefit shall be based on the clinical judgment of the hospice medical director or physician member of the hospice interdisciplinary group and the patient's attending physician, if he or she has one, regarding the normal course of the patient's illness. In 1990, the federal government added the phrase "if the illness runs its normal course" to the definition of terminal illness based on a report by the federal Government Accountability Office.[6] This report concluded that physicians were reluctant to certify patients for hospice because they were required to state in their certification that the patient had a life expectancy of six months or less.[7] The GAO Report concluded that, "[t]he statement seemed to require certainty of prognosis, whereas the establishment of long-term prognoses always involves some uncertainty."[8] CMS made the change to its regulation to prevent physicians from being discouraged to make the necessary certifications of terminal prognosis.[9] CMS later stated that the addition of this phrase was recognition of "the fact that making medical prognostications of life expectancy is not always exact."[10]

Thereafter, the number of persons electing the hospice benefit increased (as intended).[11] As with most dramatic utilization and spending increases, hospice services became a target for greater scrutiny, and the government began reviewing these services to determine if coverage requirements were being met. The United States Department of Health and Human Services Office of Inspector General (OIG) issued a report in 2009 detailing its investigation of hospice services for beneficiaries in skilled nursing facilities, which revealed additional issues that led to subsequent reviews by the OIG, Centers for Medicare & Medicaid Services (CMS), and CMS's audit contractors.[12]

*Qui tam* relators took note of the government investigations, leading to several actions brought against hospices under the FCA. In 2008, a *qui tam* suit was filed against hospice AseraCare, Inc., by three former employees. The government intervened and ultimately filed a complaint in federal court alleging that AseraCare falsely certified patients as eligible for hospice services.[13] The case proceeded to a jury, and the government's evidence included testimony from only one expert witness who testified that the medical records for the patients did not support a medical prognosis of a life expectancy of six months or less.[14] As a part of its

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defense, AseraCare called its own expert and three referring physicians, who contradicted the government's expert.[15] The government did not present any evidence that AseraCare staff falsified records or withheld information from the certifying physicians or misrepresented the patients' conditions to the physicians.[16] Despite this, the jury rendered a verdict in favor of the government.

Following the jury verdict, AseraCare made a motion for a new trial, which the court ultimately granted.[17] In its Memorandum Opinion, the district court indicated that it was granting a new trial because the government's only evidence of falsity was a physician's expert opinion testimony based on his clinical judgment. The court held that a mere difference of opinion amongst physicians, without more, was not enough to establish objective falsity under the FCA.[18] The court cited to a number of cases holding that "[e]xpressions of opinion, scientific judgments, or statements as to conclusions about which reasonable minds may differ, cannot be false."[19] Because the court had not instructed the jury on this point, it granted a new trial.[20]

Six months later, on March 31, 2016, the district court granted summary judgment in favor of AseraCare.[21] In granting summary judgment, the court noted its concern that "allowing a mere difference of opinion among physicians alone to prove falsity would totally eradicate the clinical judgment required of the certifying physicians."[22] Significantly, the court stated that "[i]f the court were to find that all the Government needed…in a hospice provider case was one medical expert who reviewed the medical records and disagreed with the certifying physician, the hospice providers would be subject to…liability any time the Government could find a medical expert who disagreed with the certifying physician's clinical judgment."[23] The district court's holding in *AseraCare* was consistent with holdings from numerous other district courts.[24]

The *AseraCare* decision was followed by two other similar hospice cases: *U.S. ex rel. Wall v. Vista Hospice Care* and *Druding v. Care Alternatives, Inc*.[25] Both were *qui tam* cases filed by former employees alleging that hospices falsely certified patients for hospice.[26] In both cases, the courts granted summary judgment to the hospices. In *Vista*, the court explained that because a certification for hospice is based on a physician's clinical judgment, an FCA claim "must be predicated on the presence of an objectively verifiable fact at odds with the exercise of that judgment, not a matter of questioning subjective clinical analysis."[27] While the relators had included testimony regarding falsification of some patient records, their experts had not reviewed those particular patient charts and the relators had failed to connect those records to any false claim. In *Druding*, the court noted that the relators failed to present evidence that the physicians had either received a kickback or did not otherwise honestly believe the patients had a life expectancy of six months or less, or that there had been alteration or falsification of patient records.[28]

The *AseraCare* decision was ultimately appealed to the Eleventh Circuit Court of Appeals.[29] The Eleventh Circuit issued its much-anticipated decision on September 9, 2019.[30] The court concurred with the district court's determination "that a clinical judgment of terminal illness warranting hospice benefits under Medicare cannot be deemed false, for purposes of the [FCA], when there is only a reasonable disagreement between medical experts as to the accuracy of that conclusion, with no other evidence to prove the falsity of the assessment."[31] In explaining its conclusion, the court indicated that while a physician's clinical judgment must be tethered to a patient's valid medical records, "the law is designed to give physicians meaningful latitude to make informed judgments without fear that those judgments will be second-guessed after the fact by laymen in a liability proceeding."[32] The court then held that in order to properly state a claim under the FCA, the plaintiff must identify facts and circumstances that are inconsistent with the proper exercise of a physician's clinical judgment (i.e., phantom patients, falsified records, information withheld from the physician, the certifying physician did not review the patient's records or condition, the physician did not subjectively believe the patient was terminally ill, or no reasonable physician could have concluded that a patient was terminally ill).[33]

The court also addressed recent cases involving cardiologists, which had been cited by the government in supplemental memoranda. One such case was *U.S. v. Paulus*, 894 F.3d 267 (6th Cir. 2018). The *Paulus* case involved a cardiologist convicted of healthcare fraud for systematically overestimating the degree of arterial blockage to justify costly stenting procedures. Although a jury convicted him, the district court entered a judgment of acquittal and granted him a new trial, reasoning that angiogram interpretations are not facts subject to proof or disproof.[34] On appeal, the Sixth Circuit reversed. The court stated that while opinions "are almost never false[,]" it went on to say that "opinions may trigger liability for fraud when they are not honestly held by their maker, or when the speaker knows of facts that are fundamentally incompatible with his opinion."[35] The court noted that while a doctor could not be faulted for misreading an angiogram, there can be liability where the government shows the doctor repeatedly and systematically saw one thing on an angiogram and consciously wrote down another.[36] The court even cited the district court's holding in *AseraCare* that

"certain good-faith medical diagnoses by a doctor cannot be false[.]"[37] However, unlike hospice eligibility, coronary artery blockage "actually exists as an aspect of reality," such that the degree of blockage can be objectively true or false.[38]

The other case cited by the government in *AseraCare* was *U.S. ex rel. Polukoff v. St. Mark's Hosp.*, 895 F.3d 730 (10th Cir. 2018)—an FCA case alleging that a cardiologist performed medically unnecessary heart surgeries. In that case, the Tenth Circuit overturned the lower court's dismissal of the action, holding that a doctor's certification that a procedure is "reasonable and necessary" can be false if the procedure was not "reasonable and necessary" under the government's definition of that phrase in the Medicare Program Integrity Manual.[39] In *AseraCare*, the Eleventh Circuit distinguished this case because the evidence in *Polukoff* showed the physician was falsely representing that the procedure was being performed based on indications set forth in applicable guidelines, when he knew they were being performed outside of those guidelines. Additionally, the Eleventh Circuit noted that, unlike the surgeries at issue in *Polukoff*, the hospice benefit was clearly tied to a physician's genuinely-held clinical opinion.[40]

The Eleventh Circuit's decision in *AseraCare* provides some clarification regarding liability when there are conflicting clinical opinions, certainly with respect to hospice eligibility cases. It gives some assurance that honestly-held clinical opinions made by physicians based upon a patient's medical records and condition cannot be second-guessed and subject a physician to liability for false claims. However, it remains to be seen how other federal appeal courts will handle this issue or how the government will respond.[41] The government and its contractors continue to pursue hospice eligibility cases despite the decision. As more cases are pursued, this area of the law will undoubtedly evolve as more decisions are issued.

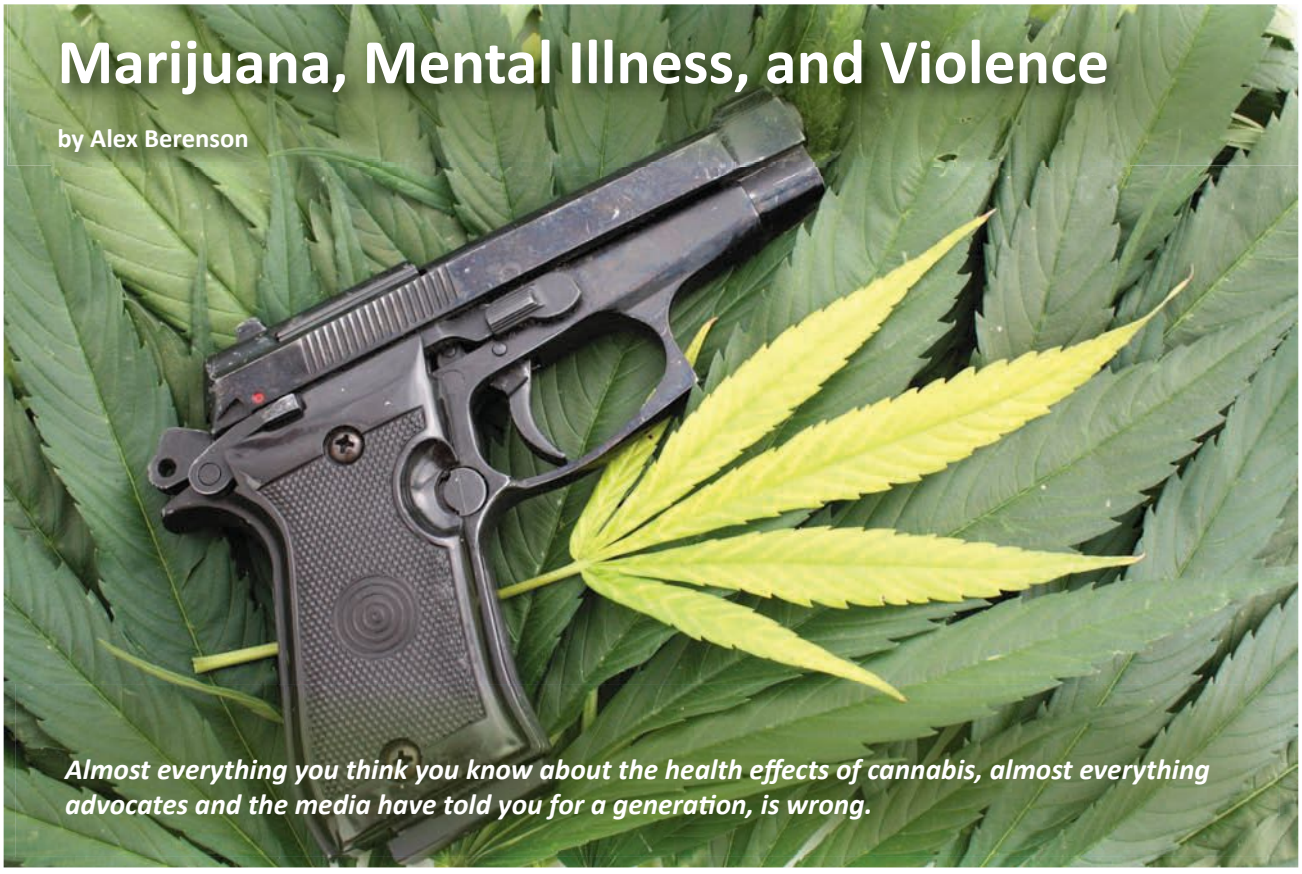
## References


1. See, e.g., 31 U.S.C. § 3729 et seq.
2. See, e.g., 18 U.S.C. § 1347; see also 18 U.S.C. § 287.
3. At common law a writ of *qui tam* is a writ through which private individuals, frequently identified as whistle blowers, who assist a prosecution can receive for themselves all or part of the damages or financial penalties recovered by the government as a result of the prosecution. Its name is an abbreviation of the Latin phrase *qui tam pro domino rege quam pro se ipso in hac parte sequitur*, meaning "[he] who sues in this matter for the king as well as for himself." The FCA contains a "whistleblower" provision. The person who acts *qui tam* is the whistleblower who is denominated as the relator acting on behalf of the government.
4. See 42 C.F.R. §§ 418.20, 418.24. Thereafter, the patient must be recertified every 90 or 60 days (depending on their total length of stay). See 42 C.F.R. § 418.21.
5. See 42 C.F.R. § 418.3.
6. See 55 Fed. Reg. 50832 (Dec. 11, 1990); see also GAO, Program Provisions and Payments Discourage Hospice Participation (Sept. 29, 1989), available at http://gao.gov/products/HRD-89-111 [hereafter GAO Report].
7. See 42 C.F.R. § 418.3 (1987).
8. See 55 Fed. Reg. 50832.
9. See 55 Fed. Reg. 50832.
10. See 70 Fed. Reg. 70534 (Nov. 22, 2005).
11. In 2000, 23% of Medicare decedents used the hospice benefit. See S. Bogasky et al., Medicare's Hospice Benefit: Analysis of Utilization and Resource Use, MEDICARE & MEDICAID RESEARCH REVIEW, Vol. 4, No. 2 (2014), at E1. In 2010, that number increased to 44%. Id. Medicare spending for hospice services jumped from $2.2 billion in calendar year 1998 to $12.1 billion in calendar year 2009. Id.
12. See OIG, Medicare Hospice Care for Beneficiaries in Nursing Facilities: Compliance with Medicare Coverage Requirements (Sept. 2009), available at https://oig.hhs.gov/oei/reports/oei-02-06-00221.pdf.
13. *U.S. v. AseraCare, Inc.*, 153 F.Supp.3d 1372, 1376 (N.D. Ala. Nov. 3, 2015).
14. Id. at 1375-76.
15. Id. at 1381.
16. Id.
17. Id.
18. Id. at 1381 (citing *U.S. ex rel. Riley v. St. Luke's Episcopal Hosp.*, 355 F.3d 370, 376 (5th Cir. 2004); *U.S. ex rel. Phalp v. Lincare Holdings, Inc.* 116 F.Supp.3d 1326, 1359 (S.D. Fl. July 10, 2015)).
19. Id. at 1383.
20. Id.
21. *U.S. v. AseraCare, Inc.*, 176 F. Supp. 3d 1282 (N.D. Ala. Mar. 31, 2016).
22. Id. at 1285.
23. Id.
24. See, e.g., *U.S. ex rel. Geschrey v. Generations Healthcare, LLC*, 922 F. Supp. 2d 695, 703 (N.D. Ill. 2012) (the relator alleged that she and others disagreed with the doctor's assessment of the patients' eligibility, but failed to allege any facts demonstrating "that the certifying physician did not or could not have believed, based on his or her clinical judgment, that the patient was eligible for hospice care."); *U.S. ex rel. Frazier v. IASIS Healthcare Corp.*, 812 F. Supp. 2d 1008, 1017 (D. Ariz. 2011) (relator failed to state a claim because he failed to "plead facts to support a reasonable inference that the physician knew the procedure was medically unnecessary at the time it was performed."); *U.S. ex rel. Phillips*, 386 F. Supp. 2d 879, 884 (W.D. Tex. 2005) (the FCA should not be used to call into question a health care provider's specific course of treatment).
25. See Memorandum Opinion, *U.S. ex rel. Wall v. Vista Hospice Care, Inc.*, Case No. 2:12-CV-245-KOB, 2016 WL 3449833 (N.D. Tex. June 20, 2016); *Druding v. Care Alternatives, Inc.*, 346 F.Supp.3d 669 (D.N.J. Sept. 26, 2018).
26. *Vista*, 2016 WL 3449833 at *1; *Druding*, 346 F.Supp.3d at 669.
27. *Vista*, 2016 WL 3449833 at *17.
28. *Druding*, 346 F.Supp.3d at 687-88.
29. The *Vista* case was appealed to the Fifth Circuit, but that appeal was subsequently dismissed in January 2018. The *Druding* case has been appealed to the Third Circuit. The case was argued on September 10, 2019, but a decision has not yet been entered by the Third Circuit.
30. *U.S. v. AseraCare, Inc.*, 938 F.3d 1278 (11th Cir. 2019).
31. Id. at 1281.
32. Id. at 1295.
33. Id. at 1297.
34. 894 F.3d 267.
35. Id. at 275.
36. Id.
37. Id.
38. Id. at 276.
39. 895 F.3d at 742. The Medicare Program Integrity Manual defines "reasonable and necessary" as: (1) safe and effective, (2) not experimental or investigational, and (3) appropriate, including the duration and frequency that is considered appropriate for the item or service, whether it is furnished in accordance with accepted standards of medical practice in an appropriate setting by qualified personnel, and does not exceed the patient's medical need. Id. (citing CMS, Medicare Program Integrity Manual, § 13.5.1).
40. *AseraCare*, 938 F.3d at 1300 n.15.
41. Missouri is within the jurisdiction of the United States Eighth Circuit Court of Appeals which has yet to rule this issue.


**MM**

# Marijuana, Mental Illness, and Violence

by Alex Berenson



***Almost everything you think you know about the health effects of cannabis, almost everything advocates and the media have told you for a generation, is wrong.***

Seventy miles northwest of New York City is a hospital that looks like a prison, its drab brick buildings wrapped in layers of fencing and barbed wire. This grim facility is called the Mid-Hudson Forensic Psychiatric Institute. It's one of three places the state of New York sends the criminally mentally ill—defendants judged not guilty by reason of insanity.

Until recently, my wife Jackie—Dr. Jacqueline Berenson—was a senior psychiatrist there. Many of Mid-Hudson's 300 patients are killers and arsonists. At least one is a cannibal. Most have been diagnosed with psychotic disorders like schizophrenia that provoked them to violence against family members or strangers.

A couple of years ago, Jackie was telling me about a patient. In passing, she said something like—*Of course he'd been smoking pot his whole life.*

*Of course?* I said.

*Yes, they all smoke.*

*So marijuana causes schizophrenia?*

I was surprised, to say the least. I tended to be a libertarian on drugs. Years before, I'd covered the pharmaceutical industry for *The New York Times*. I was aware of the claims about marijuana as medicine, and I'd watched the slow spread of legalized cannabis without much interest.

Jackie would have been within her rights to say, *I know what I'm talking about, unlike you.* Instead she offered something neutral like, *I think that's what the big studies say. You should read them.*

So I did. The big studies, the little ones, and all the rest. I read everything I could find. I talked to every psychiatrist and brain scientist who would talk to me. And I soon realized that in all my years as a journalist I had never seen a story where the gap between insider and outsider knowledge was so great, or the stakes so high.

Alex Berenson is a former *New York Times* reporter and author of 12 novels. This is adapted from a speech delivered on January 15, 2019, at Hillsdale College's Allan P. Kirby, Jr. Center for Constitutional Studies and Citizenship in Washington, D.C.
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I began to wonder why—with the stocks of cannabis companies soaring and politicians promoting legalization as a low-risk way to raise tax revenue and reduce crime—I had never heard the truth about marijuana, mental illness, and violence.

Over the last 30 years, psychiatrists and epidemiologists have turned speculation about marijuana's dangers into science. Yet over the same period, a shrewd and expensive lobbying campaign has pushed public attitudes about marijuana the other way. And the effects are now becoming apparent.

Almost everything you think you know about the health effects of cannabis, almost everything advocates and the media have told you for a generation, is wrong.

They've told you marijuana has many different medical uses. In reality marijuana and THC, its active ingredient, have been shown to work only in a few narrow conditions. They are most commonly prescribed for pain relief. But they are rarely tested against other pain relief drugs like ibuprofen—and in July, a large four-year study of patients with chronic pain in Australia showed cannabis use was associated with greater pain over time.

They've told you cannabis can stem opioid use—"Two new studies show how marijuana can help fight the opioid epidemic," according to Wonkblog, a *Washington Post* website, in April 2018— and that marijuana's effects as a painkiller make it a potential substitute for opiates. In reality, like alcohol, marijuana is too weak as a painkiller to work for most people who truly need opiates, such as terminal cancer patients. Even cannabis advocates, like Rob Kampia, the co-founder of the Marijuana Policy Project, acknowledge that they have always viewed medical marijuana laws primarily as a way to protect recreational users.

As for the marijuana-reduces-opiate-use theory, it is based largely on a single paper comparing overdose deaths by state before 2010 to the spread of medical marijuana laws— and the paper's finding is probably a result of simple geographic coincidence. The opiate epidemic began in Appalachia, while the first states to legalize medical marijuana were in the West. Since 2010, as both the epidemic and medical marijuana laws have spread nationally, the finding has vanished. And the United States, the Western country with the most cannabis use, also has by far the worst problem with opioids.

Research on individual users—a better way to trace cause and effect than looking at aggregate state-level data—consistently shows that marijuana use leads to other drug use. For example, a January 2018 paper in the *American Journal of Psychiatry* showed that people who used cannabis in 2001 were almost three times as likely to use opiates three years later, even after adjusting for other potential risks.

Most of all, advocates have told you that marijuana is not just safe for people with psychiatric problems like depression, but that it is a potential treatment for those patients. On its website, the cannabis delivery service Eaze offers the "Best Marijuana Strains and Products for Treating Anxiety." "How Does Cannabis Help Depression?" is the topic of an article on Leafly, the largest cannabis website. But a mountain of peer-reviewed research in top medical journals shows that marijuana can cause or worsen severe mental illness, especially psychosis, the medical term for a break from reality. Teenagers who smoke marijuana regularly are about three times as likely to develop schizophrenia, the most devastating psychotic disorder.

After an exhaustive review, the National Academy of Medicine found in 2017 that "cannabis use is likely to increase the risk of developing schizophrenia and other psychoses; the higher the use, the greater the risk." Also that "regular cannabis use is likely to increase the risk for developing social anxiety disorder."

Over the past decade, as legalization has spread, patterns of marijuana use—and the drug itself—have changed in dangerous ways.

Legalization has not led to a huge increase in people using the drug casually. About 15 percent of Americans used cannabis at least once in 2017, up from ten percent in 2006, according to a large federal study called the National Survey on Drug Use and Health. (By contrast, about 65 percent of Americans had a drink in the last year.) But the number of Americans who use cannabis heavily is soaring. In 2006, about three million Americans reported using cannabis at least 300 times a year, the standard for daily use. By 2017, that number had nearly tripled, to eight million, approaching the 12 million Americans who drank alcohol every day. Put another way, one in 15 drinkers consumed alcohol daily; about one in five marijuana users used cannabis that often.

Cannabis users today are also consuming a drug that is far more potent than ever before, as measured by the amount of THC—delta-9-tetrahydrocannabinol, the chemical in cannabis responsible for its psychoactive effects—it contains. In the 1970s, the last time this many Americans used cannabis, most marijuana contained less than two percent THC. Today, marijuana routinely contains 20 to 25 percent THC, thanks to sophisticated farming and cloning techniques—as well as to a demand by users for cannabis that produces a stronger high more quickly. In states where cannabis is legal, many users prefer extracts that are nearly pure THC. Think of the difference between near-beer and a martini, or even grain alcohol, to understand the difference.

These new patterns of use have caused problems with the drug to soar. In 2014, people who had diagnosable cannabis use disorder, the medical term for marijuana abuse or addiction, made up about 1.5 percent of Americans. But they accounted for 11 percent of all the psychosis cases in emergency rooms—90,000 cases, 250 a day, triple the number in 2006. In states like Colorado, emergency room physicians have become experts on dealing with cannabis-induced psychosis.

Cannabis advocates often argue that the drug can't be as neurotoxic as studies suggest, because otherwise Western countries would have seen population-wide increases in psychosis alongside rising use. In reality, accurately tracking psychosis cases is impossible in the United States. The government carefully tracks diseases like cancer with central registries, but no such registry exists for schizophrenia or other severe mental illnesses.

On the other hand, research from Finland and Denmark, two countries that track mental illness more comprehensively, shows a significant increase in psychosis since 2000, following an increase in cannabis use. And in September of last year, a large federal survey found a rise in serious mental illness in the United States as well, especially among young adults, the heaviest users of cannabis.

According to this latter study, 7.5 percent of adults age 18-25 met the criteria for serious mental illness in 2017, double the rate in 2008. What's especially striking is that adolescents age 12-17 don't show these increases in cannabis use and severe mental illness.

A caveat: this federal survey doesn't count individual cases, and it lumps psychosis with other severe mental illness. So it isn't as accurate as the Finnish or Danish studies. Nor do any of these studies prove that rising cannabis use has caused population-wide increases in psychosis or other mental illness. The most that can be said is that they offer intriguing evidence of a link.

Advocates for people with mental illness do not like discussing the link between schizophrenia and crime. They fear it will stigmatize people with the disease. "Most people with mental illness are not violent," the National Alliance on Mental Illness (NAMI) explains on its website. But wishing away the link can't make it disappear. In truth, psychosis is a shockingly high risk factor for violence. The best analysis came in a 2009 paper in PLOS Medicine by Dr. Seena Fazel, an Oxford University psychiatrist and epidemiologist. Drawing on earlier studies, the paper found that people with schizophrenia are five times as likely to commit violent crimes as healthy people, and almost 20 times as likely to commit homicide.

NAMI's statement that most people with mental illness are not violent is of course accurate, given that "most" simply means "more than half"; but it is deeply misleading. Schizophrenia is rare. But people with the disorder commit an appreciable fraction of all murders, in the range of six to nine percent.

"The best way to deal with the stigma is to reduce the violence," says Dr. Sheilagh Hodgins, a professor at the University of Montreal who has studied mental illness and violence for more than 30 years.

The marijuana-psychosis-violence connection is even stronger than those figures suggest. People with schizophrenia are only moderately more likely to become violent than healthy people when they are taking antipsychotic medicine and avoiding recreational drugs. But when they use drugs, their risk of violence skyrockets. "You don't just have an increased risk of one thing—these things occur in clusters," Dr. Fazel told me.

Along with alcohol, the drug that psychotic patients use more than any other is cannabis: a 2010 review of earlier studies in Schizophrenia Bulletin found that 27 percent of people with schizophrenia had been diagnosed with cannabis use disorder in their lives. And unfortunately—despite its reputation for making users relaxed and calm—cannabis appears to provoke many of them to violence.

A Swiss study of 265 psychotic patients published in *Frontiers of Forensic Psychiatry* last June found that over a three-year period, young men with psychosis who used cannabis had a 50 percent chance of becoming violent. That risk was four times higher than for those with psychosis who didn't use, even after adjusting for factors such as alcohol use. Other researchers have produced similar findings. A 2013 paper in an Italian psychiatric journal examined almost 1,600 psychiatric patients in southern Italy and found that cannabis use was associated with a ten-fold increase in violence.

The most obvious way that cannabis fuels violence in psychotic people is through its tendency to cause paranoia—something even cannabis advocates acknowledge the drug can cause. The risk is so obvious that users joke about it and dispensaries advertise certain strains as less likely to induce paranoia. And for people with psychotic disorders, paranoia can fuel extreme violence. A 2007 paper in the *Medical Journal of Australia* on 88 defendants who had committed homicide during psychotic episodes found that most believed they were in danger from the victim, and almost two-thirds reported misusing cannabis—more than alcohol and amphetamines combined.

Yet the link between marijuana and violence doesn't

appear limited to people with preexisting psychosis. Researchers have studied alcohol and violence for generations, proving that alcohol is a risk factor for domestic abuse, assault, and even murder. Far less work has been done on marijuana, in part because advocates have stigmatized anyone who raises the issue. But studies showing that marijuana use is a significant risk factor for violence have quietly piled up. Many of them weren't even designed to catch the link, but they did. Dozens of such studies exist, covering everything from bullying by high school students to fighting among vacationers in Spain.

In most cases, studies find that the risk is at least as significant as with alcohol. A 2012 paper in the *Journal of Interpersonal Violence* examined a federal survey of more than 9,000 adolescents and found that marijuana use was associated with a doubling of domestic violence; a 2017 paper in *Social Psychiatry and Psychiatric Epidemiology* examined drivers of violence among 6,000 British and Chinese men and found that drug use—the drug nearly always being cannabis—translated into a five-fold increase in violence.

Today that risk is translating into real-world impacts. Before states legalized recreational cannabis, advocates said that legalization would let police focus on hardened criminals rather than marijuana smokers and thus reduce violent crime. Some advocates go so far as to claim that legalization has reduced violent crime. In a 2017 speech calling for federal legalization, U.S. Senator Cory Booker said that "states [that have legalized marijuana] are seeing decreases in violent crime." He was wrong.

The first four states to legalize marijuana for recreational use were Colorado and Washington in 2014 and Alaska and Oregon in 2015. Combined, those four states had about 450 murders and 30,300 aggravated assaults in 2013. Last year, they had almost 620 murders and 38,000 aggravated assaults—an increase of 37 percent for murders and 25 percent for aggravated assaults, far greater than the national increase, even after accounting for differences in population growth.

Knowing exactly how much of the increase is related to cannabis is impossible without researching every crime. But police reports, news stories, and arrest warrants suggest a close link in many cases. For example, last September, police in Longmont, Colorado, arrested Daniel Lopez for stabbing his brother Thomas to death as a neighbor watched. Daniel Lopez had been diagnosed with schizophrenia and was "self-medicating" with marijuana, according to an arrest affidavit.

In every state, not just those where marijuana is legal, cases like Lopez's are far more common than either cannabis or mental illness advocates acknowledge. Cannabis is also associated with a disturbing number of child deaths from abuse and neglect—many more than alcohol, and more than cocaine, methamphetamines, and opioids combined—according to reports from Texas, one of the few states to provide detailed information on drug use by perpetrators.

These crimes rarely receive more than local attention. Psychosis-induced violence takes particularly ugly forms and is frequently directed at helpless family members. The elite national media prefers to ignore the crimes as tabloid fodder. Even police departments, which see this violence up close, have been slow to recognize the trend, in part because the epidemic of opioid overdose deaths has overwhelmed them.

So the black tide of psychosis and the red tide of violence are rising steadily, almost unnoticed, on a slow green wave.

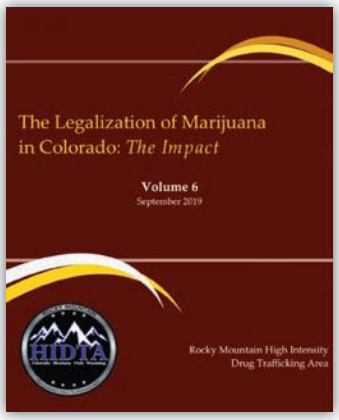
For centuries, people worldwide have understood that cannabis causes mental illness and violence—just as they've known that opiates cause addiction and overdose. Hard data on the relationship between marijuana and madness dates back 150 years, to British asylum registers in India. Yet 20 years ago, the United States moved to encourage wider use of cannabis and opiates.

In both cases, we decided we could outsmart these drugs—that we could have their benefits without their costs. And in both cases we were wrong. Opiates are riskier, and the overdose deaths they cause a more imminent crisis, so we have focused on those. But soon enough the mental illness and violence that follow cannabis use will also be too widespread to ignore.

Whether to use cannabis, or any drug, is a personal decision. Whether cannabis should be legal is a political issue. But its precise legal status is far less important than making sure that anyone who uses it is aware of its risks. Most cigarette smokers don't die of lung cancer. But we have made it widely known that cigarettes cause cancer, full stop. Most people who drink and drive don't have fatal accidents. But we have highlighted the cases of those who do.

We need equally unambiguous and well-funded advertising campaigns on the risks of cannabis. Instead, we are now in the worst of all worlds. Marijuana is legal in some states, illegal in others, dangerously potent, and sold without warnings everywhere.

But before we can do anything, we—especially cannabis advocates and those in the elite media who have for too long credulously accepted their claims—need to come to terms with the truth about the science on marijuana. That adjustment may be painful. But the alternative is far worse, as the patients at Mid-Hudson Forensic Psychiatric Institute—and their victims—know. **MM**




# The Legalization of Marijuana in Colorado: The Impact

*Volume 6, September 2019*

*by the Rocky Mountain High Intensity Drug Trafficking Area program*

**Medical and recreational marijuana are destroying the health and social fabric of Colorado the Centennial State. Efforts are already underway to introduce recreational marijuana into law in Missouri via public referendum.**

## Executive Summary

The Rocky Mountain High Intensity Drug Trafficking Area (RMHIDTA) program has published annual reports every year since 2013 tracking the impact of legalizing recreational marijuana in Colorado. The purpose is to provide data and information so that policy makers and citizens can make informed decisions on the issue of marijuana legalization.[1]

## Section I: Traffic Fatalities & Impaired Driving

- Since recreational marijuana was legalized, traffic deaths in which drivers tested positive for marijuana increased 109 percent while all Colorado traffic deaths increased 31 percent.
- Since recreational marijuana was legalized, traffic deaths involving drivers who tested positive for marijuana more than doubled from 55 in 2013 to 115 people killed in 2018.
- This equates to one person killed every 3 days in 2018 compared to one person killed every 6 ½ days in 2013.
- Since recreational marijuana was legalized, the percentage of all Colorado traffic deaths that were marijuana-related increased from 15 percent in 2013 to 23 percent in 2018.

## Section II: Marijuana Use

Since recreational marijuana was legalized:

- Past month marijuana use for ages 12 and older increased 58 percent and is 78 percent higher than the national average, currently ranked 4th in the nation.
- Adult marijuana use increased 94 percent and is 96 percent higher than the national average, currently ranked 4th in the nation.
- College age marijuana use increased 18 percent and is 48 percent higher than the national average, currently ranked 6th in the nation.
- Youth marijuana use decreased 14 percent and is 40 percent higher than the national average, currently ranked 6th in the nation.

## Section III: Public Health

- The yearly number of emergency department visits related to marijuana increased 54 percent after the legalization of recreational marijuana (2013 compared to 2017).
- The yearly number of marijuana-related hospitalizations increased 101 percent after the legalization of recreational marijuana (2013 compared to 2017).
- Marijuana-only exposures more than quadrupled in the six-year average (2013-2018) since recreational marijuana was legalized compared to the six-year average (2007-2012) prior to legalization.
- The percent of suicide incidents in which toxicology results were positive for marijuana has increased from 14 percent in 2013 to 23 percent in 2017.

## Section IV: Black Market

- RMHIDTA Colorado Drug Task Forces (10) conducted 257 investigations of black market marijuana in Colorado resulting in:
    - o 192 felony arrests
    - o 6.08 tons of marijuana seized
    - o 60,091 marijuana plants seized
    - o 25 different states the marijuana was destined
- Seizures of Colorado marijuana in the U.S. mail system has increased 1,042 percent from an average of 52 parcels (2009-2012) to an average of 594 parcels (2013-2017) during the time recreational marijuana has been legal.

## Section V: Societal Impact

- Marijuana tax revenue represent approximately nine-tenths of one percent of Colorado's FY 2018 budget.
- 64 percent of local jurisdictions in Colorado have banned medical and recreational marijuana businesses.

## References

1. https://rmhidta.org/files/D2DF/FINAL-Volume6.pdf

MM

# We Can Use Market Forces to Moderate Drug Prices

*by Henry I. Miller, MD*

In May 2018, the U.S. Department of Health and Human Services released its proposal for lowering pharmaceutical prices and reducing out-of-pocket costs. The "American Patients First" plan outlined four strategies: "improved competition, better negotiation, incentives for lower list prices, and lowering out-of-pocket costs."

Those approaches, while well-intended, seem not to have had much effect. On July 1 this year, 20 drug companies increased the list prices of more than 40 prescription drugs by an average of 13.1%, according to Rx Savings Solutions, which makes software that helps employers and health plans to choose the least-expensive medicines. That's worse than the price hikes in July of last year, when 16 companies raised the list prices of dozens of drugs by an average 7.8%.

What we really need is more competition in the marketplace, not more intrusive government interventions that would diminish pharmaceutical companies' incentives to take risks, to innovate, and to find new treatments and cures. Bringing a new drug to market currently requires 10-15 years and costs, on average, more than $2.5 billion. Is it credible that more government involvement would lower development costs, bring more drugs to market, save more lives, and make drugs more affordable? Suffice it to say that I am reminded of the quip from the late economist Milton Friedman that if the government were put in charge of the Sahara Desert, in five years there would be a shortage of sand.

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I have two proposals that would boost the number of drugs in the marketplace, which would increase both competition in the marketplace and patients' access to new medicines, and also alleviate critical shortages of old drugs in the bargain.

## Changes in FDA Policies

### *More Accelerated Approvals*

First, the Food and Drug Administration should modernize its drug review process to approve drugs more rapidly in order to increase the pool of available treatments and vaccines. One way that could be accomplished is by greater use of "accelerated approvals," which permit the FDA to issue what amounts to a limited, or conditional, approval of a new drug that is intended for a "serious or life-threatening disease" and for which there is an "unmet medical need."

Such an approval can be achieved more rapidly because it is based on clinical trials that show improvement in "surrogate endpoints" that are believed to correlate with clinical benefit but have not yet shown efficacy on a "definitive" health endpoint such as increased longevity or an actual reduction in the incidence of heart attacks. Examples of surrogate endpoints are the shrinking of a tumor, improvement in a laboratory value such as blood urea nitrogen (BUN), or greater ability to ambulate in patients with a neurodegenerative disease.

Following accelerated approval, the drug sponsor (company) must perform confirmatory trials to prove to the FDA that the medicine is effective in meeting a definitive clinical endpoint (such as greater longevity), at which time the approval is converted to a standard, unconditional approval. If the studies are not done or they fail to provide such confirmation, the FDA can withdraw the drug from the market.

### *Better Management and Discipline at the FDA*

Another way to get more drugs into the marketplace is by means of good, old-fashioned, conscientious management. The FDA is notorious for pushing the envelope of its statutory authority in ways that stifle innovation in drug development. Although there exists a legal requirement only to show that a new drug is safe and effective, the agency has invented new criteria, including a demonstration of superiority, which it applies arbitrarily. However, proving that a drug is better than existing drugs often is much more difficult and vastly more expensive than just proving that it is safe and effective, because if two medicines' efficacy differs only marginally, the clinical trials must be very large in order to attain statistical significance. Drugs useful for some patients will fail to gain approval if this new criterion is widely implemented, putting a damper on competition in the drug market and boosting prices.

FDA's management should also exert its influence on the appearance and uptake in the marketplace of "biosimilars," which can be thought of as generic versions of "biologics" -- drugs that are complex biological molecules derived from living cells; typical examples include vaccines, gene therapy, cancer and arthritis drugs, and allergenic products. Biosimilars are projected to be priced between 10 and 51 percent less than corresponding brand-name biologics. Economist Wayne Winegarden estimates that small-molecule generic drugs "saved the U.S. health system $1.67 trillion between 2007 and 2016 alone," and according to his analysis, with increasing market share of currently approved biosimilars, the savings could run well into the billions.

One obstacle to physicians' prescribing of biosimilars is a whispering campaign against them by makers of the more expensive brand-name products. The legislation that established the regulatory pathway for biosimilars states explicitly that a biosimilar must be highly similar to, have the same mechanism of action as, and have no clinically meaningful differences from the reference product – and FDA is has been strict about ensuring those conditions are met -- but that hasn't deterred producers of brand-name biologics from raising hypothetical concerns to prescribers and patients about the safety and efficacy of biosimilars. The FDA (and possibly the Federal Trade Commission) should ensure that public statements made about biosimilars by competitors are neither untrue nor misleading.

## Reciprocity of Drug Approvals

My second proposal – reciprocity of drug approvals based on approval by foreign regulatory agencies that have approval processes comparable to the FDA's – would increase competition and access to a greater number of drugs on the market in the United States, thereby putting downward pressure on prices.

Most important of all, reciprocity would benefit patients directly. The detrimental effects of delays in FDA approval of certain new drugs already available in other industrialized countries are well documented. One notable example is the FDA's 2015 approval of Fluad, a flu vaccine that contains an adjuvant (MF59), which boosts the immunogenicity of the vaccine. It is intended for use in the elderly, whose immune response to flu vaccines is often poor, with devastating effects. People over age 64 account for 80-90 percent of seasonal flu-related deaths and 50-70 percent of flu-related hospitalizations in the United States.

Fluad was initially approved in Italy in 1997, and at the time of its U.S. approval in November 2015, had been licensed in 38 countries, including Canada and 15 European nations. The lengthy delay in the drug's availability in the United States surely resulted in thousands of avoidable deaths.

Another example of a lethal regulatory delay is the sorry saga of a drug called pirfenidone, used to treat a pulmonary disorder called idiopathic pulmonary fibrosis (IPF), which used to kill tens of thousands of Americans annually.

The cause of the disease is unknown and there were no drug treatments approved for it in the United States until October 2014, although pirfenidone had already been marketed in Europe (since 2011), Japan (2008), Canada (2012) and China.

Pirfenidone was approved in the EU on the basis of three randomized, double-blind, placebo-controlled studies, one conducted in Japan and the other two in Europe and the United States.

In spite of a recommendation for approval by an FDA advisory committee (comprised of outside experts) in 2010, agency officials opted not to approve the drug and demanded another major clinical study. The results, published in May 2014 were impressive and the FDA finally approved the drug without fanfare in October 2014. But between 2010 and pirfenidone's approval, more than 150,000 patients died of IPF in the United States, many of whom could have benefited from the drug, had it been available.

The Fluad and pirfenidone examples illustrate an endemic problem at "gatekeeper" regulatory agencies — those, like the FDA, that must grant an affirmative approval before a product can be legally marketed.

How would reciprocity work? Reciprocity of drug

approvals with certain of the FDA's foreign counterparts that have comparable drug approval regimes would cause an approval in one such country to trigger approval in the United States upon application by the foreign drug manufacturer or licensee (subject to the creation of approved labeling in appropriate format, etc.). That would make more drugs available sooner in the United States, increase competition and put downward pressure on prices.

Reciprocity of foreign approvals would also help to alleviate the pressing problem in the United States of shortages of certain critical drugs, many of which have been essential in medical practice for decades. The majority are generic injectable medications commonly used by EMTs and in hospitals, including analgesics, cancer drugs, anesthetics, antipsychotics for psychiatric emergencies, and electrolytes needed for patients on IV supplementation.

Hospitals are scrambling to assure adequate supplies of drugs that are in short supply, or to find substitutes for them. The FDA is severely limited in what it can do to address shortages. The agency's app to enable health-care providers to keep current on shortages informs them about the problem but doesn't actually remedy it. Reciprocity of approvals would make numerous needed alternative drugs available. It could have been in place decades ago if only the FDA had met its long-standing commitment to pursue it through the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).

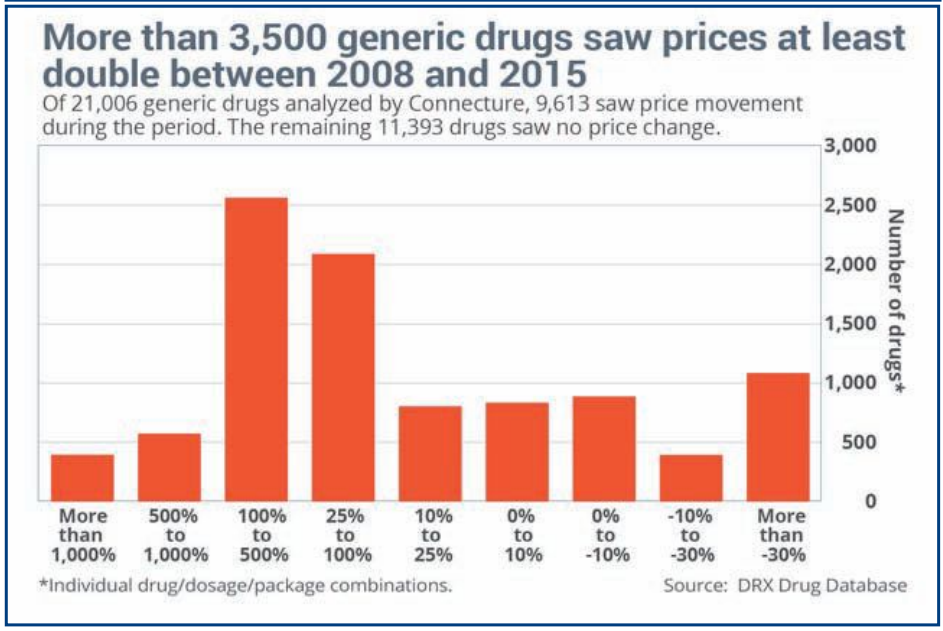
There has been some progress on harmonization at the margins. A number of countries now have a common standardized dossier for seeking approval of new drugs, the United States accepts research conducted in other countries to support applications for the approval of new drugs and devices, and the FDA has established Good Manufacturing Practices for foreign production facilities.

The ICH's agenda (supposedly) includes reciprocity of drug approvals among certain governments, but generations of FDA officials have resisted any such "delegation" of their responsibilities. When a senior European regulator was asked about the extent of the FDA's cooperation on this issue, she quipped, "It's like discussing the Thanksgiving dinner menu with the turkeys."

The FDA has improvised procedures for importing drugs approved and marketed abroad that have not been approved in the U.S., but that "enforcement discretion" approach – a kind of ad hoc reciprocity -- is legally questionable. In a footnote to the agency's October 2013 Strategic Plan for Preventing and Mitigating Drug Shortages, FDA acknowledged its awareness of a relevant court decision, Cook v. FDA (D.C. Circuit, Case No. 12-5176), in which the court prohibited FDA from using enforcement discretion to permit the importation of an unapproved drug for capital punishment execution, because the law is clear that an unapproved drug cannot come through U.S. Customs for marketing. The FDA's terse comment, "We are currently reviewing the decision in the context of our drug shortages program," belies the existential importance of that decision.

Allowing market forces – i.e., competition -- to put downward pressure on drug prices is likely to be more fruitful, and to have fewer unintended effects, than heavy-handed government interventions such as price controls. Reciprocity of medical-product regulatory decisions, more accelerated approvals, and improved management of the FDA would move us in that direction. **MM**

**1 Picture = 1,000 Words**



# Breaking the Chains: Human Trafficking and Health Care Providers

*by Mary Elizabeth Sutherland, MD*

## Human Sexual Trafficking Case History

An angry 15-year-old glared at the medical team and her few words were littered with curses. An older woman, with vague claim of caregiver, hovered anxious and irritated in the background. The patient had been transferred to the pediatric intensive care unit for management of an intentional overdose. When the patient's history was obtained from secondary sources it was discovered she had been previously sold for sex by the adults in her life. Whether she was still being sexually trafficked was unclear. The patient was extraordinarily vulnerable and in desperate need of physical and psychosocial care.[1]

## Introduction

The above is an example of the intersection of the healthcare system and nefarious human trafficking. There is a growing awareness of this widespread phenomenon as a human rights atrocity and public health crisis throughout the United States and the rest of the world. There is still uncertainty how the healthcare community can best respond. The situation is dire for the victims and it demands the attention of the medical profession.

## Background

There are multiple definitions of human trafficking all with similar features. The official federal description of "severe human trafficking" is as follows: "Sex trafficking in which a commercial sex act is induced by force, fraud, or coercion, or in which the person induced to perform such act has not attained 18 years of age; or the recruitment, harboring, transportation, provision, or obtaining of a person for labor or services, through the use of force, fraud, or coercion for the purpose of subjection to involuntary servitude, peonage, debt bondage, or slavery." [2]

These definitions have important legal implications that are not as directly applicable in the health professions. There are portions of these statements that do have particular relevance. First, most anyone can be trafficked. While some demographics make a person more susceptible to trafficking, the person can be any age, sex, or socioeconomic level.[3] Poverty and lower socioeconomic background increase the risks. Second, no movement is required across national or even state boundaries. Tragically, some patients are trafficked from their own homes.[4] Third, the words "force, fraud, or coercion" mean that kidnapping and physical restraints such as chains or ropes are not essential components. Psychological methods alone may offer the oppressors power over the vulnerable. More often manipulation, fear, and verbal threats are sufficient to control these victims rather than brute force.[5] Fourth, note the exception in the sex trafficking definition: any patient under 18 being sold for sex, is by law, a victim of trafficking.

The scope and severity of the crisis is elusive. According to the FBI, human trafficking is the third largest criminal enterprise worldwide.[6] Many organizations decline to cite statistics as any estimates are uncertain. Studies have shown that the victim described in the introduction is not an isolated or rare occurrence. Interviewed survivors confirm that many victims of human trafficking utilize the healthcare system during their abuse. This puts health care professionals in unique position to influence the outcome for the abused who present as patients.[7] There are barriers to identification and being of assistance. These barriers can be divided into those that reside with the trafficked patient and those specific to the healthcare team. While there is limited control over patient related factors, efforts can be made to remove the provider barriers to care.[8]

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## Making the Diagnosis of 'Human Trafficking"

The term "human trafficking" often conjures up images of dramatic kidnapping of young women, crossing international borders, and people in physical captivity. The reality is often much more subtle. It is vital to abandon stereotypes that keep providers from diagnosing patients. Instead we must focus attention on the vulnerabilities make a patient susceptible to these abuses. These risk factors are often ill-defined but it is imperative they always be considered.

Healthcare professionals must understand the many presentations of human trafficking. It should always be among the possible diagnoses just as physical abuse is. The duty lies with the provider to have a high level of suspicion. Perhaps health care providers are not seeing human trafficking because they are not thinking about it. Efforts to educate the medical field on this health topic should be encouraged both on the individual and systemic level.[9, 10]

Most important to identify these patients, health care teams need to look for vulnerabilities. International patients, with language and cultural barriers, are at increased risk, but also patients that have run away or homeless.[11] Individuals with drug addictions or history of prostitution are at higher risk.[12] Patients who do not control their own money or documents, have little understanding of local geography, or who are inappropriately dependent on another person should raise the index of suspicion.[8] Other signs may be similar to physical abuse situations such as the purposed mechanism of injury not being consistent with the pathology, delay in seeking medical care, or traumatic injuries. Patients may suffer from PTSD symptoms, somatic complaints, or similar stress related illnesses.[13] Lack of trust in authorities and/or limited English proficiency can also challenge identification.[8, 12, 13] The provider's 'gut' instinct that something is "off" should not be disregarded.

For patients who are being trafficked sexually, look for frequent/untreated sexually transmitted infections, vaginal trauma, and unplanned pregnancy. These patients are at higher risk for pelvic inflammatory disease and toxic shock syndrome. They often are forced to work with retained tampons or similar impacted products in order to continue generating revenue during menstruation.[12] If the patients are controlled by a pimp, they may have signs of ownership on their bodies such as specific tattoos showing that they "belong" to their trafficker.[14] If labor trafficking is suspected, the focus should be on work-related injuries, exhaustion, and environmental exposures.[13]

Figure 1.

### The Provider Role

**Responsible For:**

- Adding human trafficking to the differential
- Recognizing the vulnerabilities that may signify a patient has been trafficked
- Using compassionate trauma-informed care
- Documenting carefully

**Not Responsible For:**

- Proving human trafficking
- Rescuing patients

## Providing Care

Once a patient is identified as a possible victim of human trafficking, the reporting and treatment process can be amorphous. Care of trafficked patients requires a multifaceted, team-based, holistic approach. While this may sound overwhelming, most of the strategies are those inherent to quality medicine (Figure 1).

It can be difficult to identify the appropriate actions after a patient has been recognized as trafficked and is willing to cooperate with the medical team. The specific pathway will vary from institution to institution. There are some basic principles that can guide all actions. First, ensure that there is no immediate danger to the patient and medical team. Refrain from direct confrontation with possible traffickers. Patients should be given a chance to speak with a provider alone and appropriate interpreter services should be available. Second, call for assistance. This may start with the social worker but will eventually also include law enforcement. There are also multiple nonprofits that assist the trafficked. If there is no local assistance, the national hotline should be contacted immediately. Third, thorough, accurate, documentation is essential and may be relied upon later in court[15] (Figure 2).

While determining if the patient is a victim of human trafficking, the presenting problem must be adequately addressed. That complaint must be given full attendance and credence.[15]

Every effort should be made to avoid re-traumatizing the patient. Relationships and trust are the essential foundation of medical care and especially so in this victimized population. Patients are typically not bound to their oppressors by physical force (chains) but by

Figure 2. Resources
*Photo Credit: Phoebe James, BSW*

## Resources

**For Survivors:**

National Human Trafficking Hotline: 1-888-373-7888

The Covering House: thecoveringhouse.org

The Polaris Project: polarisproject.org

**For Providers:**

Dignity Health: dignityhealth.org/hello-humankindness/human-trafficking/victim-centered-and-trauma-informed/using-the-pearr-tool

Stop Human Trafficking: stoptraffickingmo-il.org/awareness.html

HEAL Trafficking: healtrafficking.org

manipulative and exploitive relationships. Constructive and curative relationships are an essential component of the solution. By this logic, clinics, hospitals, and ERs should be seen as places of safety and sanctuary. [15, 16]

The desire to fix and save are innate to the healthcare profession. Trafficking may be a situation when these impulses should occasionally be held in check. The patient presenting with history of trafficking has been controlled and manipulated in extreme ways. For a variety of reasons, they may not want to deal with their trafficking situation at that time. A patient, over the age of 18, has the right to decline assistance and that right should be respected. A patient may not be aware that they have been trafficked or identify as a victim. Developing a level of trust and respect will be critical regardless of the patient's initial response.[15,16]

On an individual and public health level prevention of the inhumane and destructive impact of human trafficking should be the ultimate goal.[7]

## Conclusion

Human trafficking is unlawful and a public health problem that demands the attention of medical teams everywhere. Too many patients are entering and leaving the healthcare system undetected. In practice, the identification of human trafficking is often difficult with significant overlapping factors. Specific institutional protocols and education for handling human trafficking are lacking. Advocates need to continue to urge systems to have a formal plan for identification and care for these vulnerable patients while striving to be prepared personally to assume those provider roles.

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**MM**

# Beyond Basic at the Stowers Institute for Medical Research

*by Kimberly Bland, PHD & Anissa Anderson Orr, BA*

***Investigating fundamental processes underlying health and disease with a commitment to training the biomedical workforce.***

Stories of breakthrough medical discoveries often evoke a sense of linearity, whereby fundamental discoveries are connected to new treatments or cures for patients by a straight line. In many cases, however, the path to discovery is more like a circle linking patients, physicians, and scientists together in a continuous feedback loop.

The Stowers Institute for Medical Research plays an important role in this dynamic process, with its commitment to basic biomedical research, education, and training.

The Stowers Institute emerged on the scientific scene in 1994, when the late James "Jim" E. Stowers Jr., the founder of American Century Investments, and his wife Virginia G. Stowers, established the Institute, dedicating their personal fortune to improving human health through basic research.

Kimberly Bland, PhD, (left) head of science communications, and Anissa Anderson Orr, BA, (right) science writer, Stowers Institute for Medical Research, Kansas City, Missouri.
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Over the years, the Stowers Institute's unique philosophy and environment, which fosters interdisciplinary collaboration and encourages outside-the-box thinking, has been the driving force behind promising insights and discoveries that have advanced our understanding of health and disease.

"The nature of science is that you just don't know what the next discovery's going to be, and I think the most exciting opportunities for discovery and innovation are from that interface between people who have different backgrounds," says Betty Drees, MD, FACP, FACE, president of Stowers Graduate School and Dean Emerita of the University of Missouri-Kansas City (UMKC) School of Medicine. "Having an institution like Stowers in this community just provides another spark towards that innovation and creativity and discovery."

## A Unique Space for Basic Research

The Institute's 600,000-square-foot research facility, situated on the former campus of the Menorah Medical Center in Kansas City, Missouri, was designed to provide state-of-the-art laboratory space, equipment, and technical support, and to encourage collaboration between scientists. The first laboratories opened in 2000. In 2009, the Institute added a 280,000-square-foot complex in South Kansas City to accommodate additional support functions and storage facilities.

On a typical day, about 500 Stowers members, most of them scientists, fill the Institute's labs and halls—sharing ideas over coffee, meeting with colleagues from other institutions at seminars and symposia, and passing on their knowledge to students. Together, they work on more than 150 ongoing research projects, many of which fall into the general research areas of chromatin and gene expression regulation, chromosome structure and cell division, developmental neuroscience, stem cell biology and regeneration, and computational biology and

The Stowers Institute for Medical Research in Kansas City, Missouri.

biomathematics. At a place where crossover is encouraged, most of the 22 Stowers laboratories headed by principal investigators (PIs) conduct research in multiple areas.

In addition to PI labs, the Institute has 16 scientific support teams, comprising more than 100 highly-trained scientists, to give researchers easy access to scientific infrastructure, technology and expertise—from unusual model organisms such as cavefish and the starlet sea anemone to sophisticated gene sequencing technology. Having these resources and expertise at their disposal saves researchers precious time they can reinvest in their work. In addition, Stowers research is largely supported by an endowment established initially by Jim and Virginia Stowers. This type of endowment funding allows Stowers researchers to focus more energy on scientific research rather than grant-writing efforts to secure their own funding.

## Training Future Scientists

Education is an important part of the Stowers Institute mission. The Institute launched a graduate training program in the fall of 2011, and offers a summer research program for undergraduate students as well as a postdoctoral training program. Over the last decade, the Institute has trained hundreds of undergraduate, predoctoral, and postdoctoral researchers for scientific careers.

The Graduate School of the Stowers Institute for Medical Research provides a rigorous research program that emphasizes critical thinking combined with in-depth experience in the latest methodologies. The competitive program, which offers a PhD in Biology, enrolls an average of eight predoctoral researchers each year. Graduates of the program have gone on to take biomedical research positions at places such as Genentech, the University of Oregon, and Washington University in St. Louis. The Institute also offers PhD training in affiliation with graduate programs at several other research institutions.

The Institute's postdoctoral researchers collaborate with Stowers investigators and scientific support teams to gain the skills and credentials they need to launch independent research careers. Stowers postdocs can take advantage of outstanding interdisciplinary expertise and opportunities to learn new techniques to expand and accelerate their own research.

The Stowers Summer Scholars Program offers undergraduate students pursuing a degree in the biological and physical sciences, as well as recent graduates, the opportunity to immerse themselves in a research topic over the summer. The eight-week program accepts about 30 Scholars each year.

## From Bench to Bedside

In addition to researchers in PhD programs, students from local MD-PhD programs as well as practicing physicians have performed research in Stowers labs. These opportunities provide clinically-focused trainees and

healthcare providers exposure to the more basic side of biomedical research.

Wanting to delve deeper into the mechanisms of cancer, Erin Guest, MD, now an associate professor in the Department of Pediatrics at the University of Missouri-Kansas City and Children's Mercy Hospital in Kansas City, Missouri, trained in the Shilatifard Lab at Stowers (now at Northwestern University Feinberg School of Medicine) in 2009. She worked there while a hematology/oncology fellow at Children's Mercy, with support from a young investigator award from Alex's Lemonade Stand Foundation.

For the next three years, Guest juggled seeing patients in the hospital clinic once a week and attending educational conferences and meetings, with four days immersed in the lab. Having "absolutely no prior lab experience," Guest relished the hands-on experience in basic bench techniques and learning about the Mixed Lineage Leukemia (MLL) gene. Chromosomal breaks in the gene can cause an aggressive form of leukemia. Guest studied how it functioned, what proteins it made, and what causes it to break.

Guest remembers a patient she treated with an MLL gene break – a four-month old baby who initially responded well to treatment, but ultimately didn't survive.

"Her mother, during one of the last times I said goodbye to her, said, 'I just want you to take my child's blood, take it to Stowers and do research on it.' That to me was really meaningful and inspirational," she says.

The conversation spurred Guest to establish a biorepository at Children's Mercy to bank patient samples of blood, leftover tumor samples, DNA, and clinical data, and be open to research scientists. Guest has sent samples from more than 100 patients to Stowers scientists Linheng Li, PhD, and John Perry, PhD, (formerly a Li Lab postdoc, now at Children's Mercy Hospital), for their research on cancer stem cells. She also runs a National Cancer Institute-sponsored clinical trial studying a new drug for infants with the MLL gene break.

The busy pediatric oncologist says she frequently draws on her Stowers training to conduct research of her own and to make educated treatment decisions.

"Every single cancer is different, and for each patient an oncologist has to look and find out what's to know about the disease, and what's known about the genomics of the disease and assess different treatments," she says. "Then we give families possible options. For me, having that basic science exposure helps me search the literature, read it, and understand it with more of that scientific mindset."

## Learning Collaborative Science

Kristin Melton, MD, associate professor in the Department of Pediatrics at the University of Cincinnati, was a practicing neonatologist at Children's Mercy Hospital when she secured a spot in the lab of Paul Trainor, PhD, who studies neural crest cell development and its relationship to craniofacial, heart, and gastrointestinal birth defects and disorders. His work aligned closely with the problems Melton saw in her patients on a day to-day basis.

"During development, many organs are developing together at the same time," she says. "When we see newborns with problems, we'll see, for example, that they have craniofacial abnormalities, and abnormalities of their hands, or abnormalities of their kidneys, or other areas. Understanding how those organs develop together was really helpful and interesting."

Melton conducted research in the Trainor Lab from 2001 to 2007, supported for three of those years by a National Cancer Institute K08 fellowship, which provides funding and protected time to early career clinician scientists. She typically worked three weeks in the hospital caring for newborns and babies and spent the fourth week doing research.

While in the Trainor Lab, Melton worked with many tools and techniques that were innovative at the time, such as using microarrays to identify genes important to craniofacial development and developing a mutagenesis screen in mice to identify novel genes in early craniofacial development.

"It was very productive time," Melton says. "We identified and evaluated about 10 different genes."

Now, with her Stowers training behind her, Melton works as a neonatologist at Cincinnati Children's Hospital Medical Center, where she helps direct the hospital's neonatal-perinatal fellowship. While she's no longer conducting basic research, she says her time in the lab taught her the essentials behind great science.

"I learned how collaborative science works," she says. "I worked with many different people and learned from different methods, and from people who were working in fields that were very different from my own. At Stowers, there's a lot of sharing and collaboration going on that helps you build your science. I think it's a great model."

## A Diversity of Ideas

The Stowers Institute also benefits from the perspectives physicians and budding scientists bring to its labs—whether it's a fresh take on a thorny research problem or first-hand experience treating patients with a

The Stowers Institute for Medical Research houses more than 20 independent research programs and 16 scientific support teams.

disease or developmental process that's being studied.

For his part, Trainor says his lab has prospered from relationships with visiting physicians and students in training. Melton, for example, shared how developmental disorders affect the tiniest patients.

"I don't see human patients, and I'm not responsible for diagnosing or treating them," Trainor says. "So any time you have someone that comes into the lab with a completely different experience, it is incredibly enriching for any of the projects we do. And that's true of any type of research collaboration that you undertake. Different perspectives lead to diversity of opinions and a diversity of ideas."

The Trainor Lab has been working on Treacher Collins syndrome, a developmental disorder that is characterized by malformation of the ears, eyelids, cheekbones, and jawbones. The condition recently rose to prominence with the book and movie Wonder, where the main character has Treacher Collins syndrome. Children with the condition often face years of reconstructive surgery that is never fully corrective. The Trainor Lab is investigating the roles of the TCOF1, POLR1C and POLR1D genes in neural crest cell development as a mechanism for understanding the origin of the birth defect and how to prevent and repair it.

Trainor and his team often attend retreats for individuals with Treacher Collins syndrome and their families. Listening to families share their stories and day-to-day challenges motivates the team to do their best research. The team also educates families about their latest findings and explains the genetics behind the disorder.

"We've come to really understand and appreciate that one of the most critical things for affected individuals and their families is just a much deeper understanding of why the condition occurs and how it occurs," Trainor says. "Parents often feel incredibly guilty if they have a child who's born with a developmental difference, and it's very natural for them to blame themselves. But, the more knowledge they have about how the condition occurs, the more it helps them realize that it wasn't their fault."

For Trainor, this kind of back-and-forth discussion is a form of translational medicine, though not in the traditional sense.

"Sometimes people think about translational medicine purely in a clinical treatment sense, but I think it is much, much broader than that, and it can involve simply the communication of new knowledge to people that matter – the patients," Trainor says.

## Why Basic Research Matters

Looking to the future, the Stowers Institute will continue to support and conduct basic research, strive to enable innovative approaches to improve human health, and educate and train researchers in preparation for scientific, biomedical, and related professions. Studying fundamental questions about biology, health, and disease with a broad, long-term perspective yields data and discoveries that are the stepping stones for future medical advances. Many times, these outcomes are completely unpredicted at the outset of the research, yet history shows they happen on a regular basis.

"There are many examples of basic science discoveries that are essential to our understanding of clinical medicine, such as how cholesterol is metabolized, or blood clots, or cells become cancerous," Drees says. "You can't practice medicine without understanding basic science." **MM**

*Don't Be a Victim of Predatory Publishers!*

# Selecting a Journal for Publication: Criteria to Consider

*by Amy M. Suiter, MLS & Cathy C. Sarli, MLS*

***Publishing in journals that are not reputable can diminish the credibility of your research and limit your career.***

## Introduction

Digital technologies and new publishing models such as Open Access coupled with the democratization of publishing worldwide has transformed the traditional print journal model for communication and dissemination of knowledge. In spite of the vast array of publishing opportunities in today's digital world that allow authors to reach a wider audience, authors face an unprecedented challenge when selecting a journal to publish their research. There are now over 80,000 academic, peer-reviewed English language journals currently active as of July 2019 and 30,000 of these journals are classified under Medicine and Health.[1]

In light of the proliferation of journals, some journals have come under increased scrutiny recently with terms such as questionable, predatory, pseudo, deceptive, unscrupulous, illegitimate, or dishonest, used to describe these journals.[2-3] Per Cobey,[4] et al., there is no standardized definition of questionable journals but the International Committee of Medical Journal Editors (ICMJE) offers a description: "These journals (predatory or pseudo-journals) accept and publish almost all submissions and charge article processing (or publication) fees, often informing authors about this after a paper's acceptance for publication. They often claim to perform peer review but do not and may purposefully use names similar to well established journals."[5] Additional characteristics of these journals described by Masten and Ashcraft include offering no services such as "expert peer-review, editing, archiving, indexing, and promising almost instant publication."[6] Shamseer, et al., note 13 salient characteristics of potential predatory publishers such as no retraction policy, homepage language targeting authors, scope includes non-biomedical subjects alongside biomedical topics, manuscript submission via email, and others.[7]

In December 2016, the International Committee of Medical Journal Editors (ICMJE) announced revised recommendations for authors: "A growing number of entities are advertising themselves as 'medical journals' yet do not function as such (predatory journals)." The advice to authors was: "Authors have a responsibility to evaluate the integrity, history, practices and reputation of the journals to which they submit manuscripts." The National Institutes of Health (NIH) issued a notice in November 2017 reporting an increase in journal articles generated with NIH-funded research published in journals or by publishers that do not follow best practices.[8] NIH issued several recommendations for authors to ensure the credibility of their research findings when publishing:

- Adhere to the principles of research integrity and publication ethics;
- Identify journals that follow best practices promoted by professional scholarly publishing organizations; and
- Avoid publishing in journals that do not have a clearly stated and rigorous peer review process.

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How can authors evaluate the integrity, history, practices and reputation of journals? There is no reliable list of good vs. bad journals, nor is there an automated decision-aid tool to use for identifying journals that are suitable for publication. We recommend that authors begin their list of potential journals by considering the journals they use for their research or clinical care. Other potential journals include journals from publications that authors cite in their research, journals they review for, and journals associated with their professional organizations. Mentors and colleagues may also be able to provide insight as to which journals are regarded as relevant for an area of research or are recommended for tenure and promotion purposes. Consultations with mentors and colleagues can be especially important for early-career authors and authors tackling a research topic outside their primary field. Other criteria to consider are noted below.

## Criteria for Evaluating a Journal

### *Scientific Rigor*

A key indicator of journal quality is the scientific rigor of the publications published in the journal. When considering publishing in a new or unfamiliar journal begin with a review of publications published over the past few years to assess details such as the purpose of the research, design and methodology, data analysis, results, and discussion, all of which can lend insight as to scientific quality. Tables and figures should be clearly marked, legible and appropriate for the data. References should be comprehensive and current. The procedures used by the journal for ensuring scientific rigor during the peer review process also lend insight as to commitment to scientific rigor. Plagiarism checks using software such as iThenticate, using different statistical testing to confirm data validity, and applying forensic tools to detect image manipulation are examples of practices that reputable journals follow to ensure scientific rigor.

Another clue as to scientific rigor is whether the journal requires use of recognized guidelines for reporting of research. Reporting guidelines help to ensure the quality of scientific research and enhance the replicability of the research. Examples of reporting guidelines are CONSORT, PRISMA, STROBE, to name a few. As of July 2019, there are over 400 reporting guidelines per Equator Network.[9] A similar requirement by journals is registration of clinical trials before the time of first patient enrollment to be considered for manuscript review. Transparency of journal practices and policies for data sharing is another factor to consider for assessing scientific rigor. Data sharing is integral for ensuring that science is transparent and reproducible, and promotes the integrity of research and fosters public trust. A recent Pew Report in 2019 found that a majority of U.S Adults (57%) trust scientific research findings more if the researchers make their data publicly available.[10]

### *Editorial Quality*

Editorial quality noted in publications including editorials, can provide clues as to journal quality. Misspellings, grammar and punctuation errors, or lack of clarity and cohesiveness in writing is indicative of lack of editorial oversight and reviewer commitment. These clues may signal a journal that is not appropriate for publication. Titles and abstracts themselves can also be revealing as to editorial quality—a title that is not descriptive or an abstract that needs to be read more than once may be a warning sign.

### *Peer Review Process*

Transparency as to the peer review process is a benchmark of journal quality. A reputable journal will fully disclose the peer review process including criteria used for peer review, selection of reviewers, the type of peer review, timeframes for the peer review, and how the peer review process is handled by the editorial board. Additional details such as how conflicts of interest are handled, confidentiality, and other ethical standards for peer reviewers should also be available from the journal website.

### *Ethics*

A quality journal will include information as to issues such as plagiarism, conflicts of interest, internal review board approval, informed consent, human and animal subject research, confidentiality, fraud, salami (or segmented) publications, ghost authorship, data and image manipulation, and other ethical considerations. A journal should include information as to ethics on the journal website, what their expectations are of authors and how they address these issues. Reputable journals endorse guidelines and best practices for publishers such as the International Committee of Medical Journal Editors (ICMJE), Committee on Publication Ethics (COPE), and the World Association of Medical Editors (WAME).

### *Editorial Board Members*

A review of the journal editorial board can reveal valuable insights as to the quality of a journal. Editorial board members should be known as established experts in the field related to the aim and scope of the journal,

affiliated with known institutions, and hold appropriate academic credentials. Contact information for editorial staff should also be available. If information is missing from the journal website or if there is no contact information for editorial board members, additional review is recommended before submitting a manuscript for peer review.

Another clue related to editorial quality is editorials authored by the Editor-in-Chief or members of the editorial board. Editorial board members from reputable journals will contribute frequent and thoughtful editorials that provide context or significance to publications for a specific issue or discuss updates in journal policies for authors and readers.

### *Journal Reputation/Business Model*

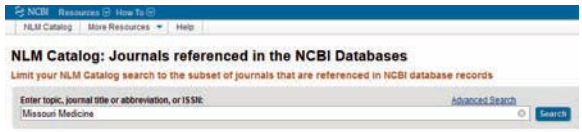
The reputation of a journal includes the publisher of the journal, the societal organization that sponsors the journal, aim and scope, mission statement, among other criteria. The publisher of a journal or the sponsoring society can lend strong credence to the quality of a journal. The aim and scope should be clearly stated and other information such as a mission statement or sponsoring organizations helps to assess the reputation of the journal. The business model of a journal should be evident and if there are fees for publication, the fees should be clearly stated on the journal website—in other words, there should be no surprise fees after submission of a manuscript for peer review.

### *Author Rights and Copyright*

The journal policy as to author rights and copyright is another benchmark of a quality journal. Copyright is a bundle of rights that allows authors to use, disseminate, display or modify the work in any medium. Up until 20 years ago, authors routinely transferred all rights to their work to the journal publisher upon publication. Many journals allow authors generous uses of the work after publication and in some instances, will allow authors to retain full rights to the work. Authors are advised to anticipate any future re-uses of their publications before selecting a journal and signing a copyright agreement form. Some authors are required to comply with public access mandates from organizations such as the National Institutes of Health (NIH) or the National Science Foundation (NSF). If a journal does not allow for compliance with public access mandates, authors will need to consider another journal. Some journals allow oral rights to the work or reuse of a figure or table in a subsequent work, or posting of the work on a repository; others do not. Journals may also stipulate various uses based on the version of the work (pre-print, post-print, and final published version). Transparency of a journal's copyright policies for authors is indicative of a quality journal.

Figure 1. How to Check for MEDLINE® Indexing Status

1. Go to the National Library of Medicine (NLM) Catalog: Journals Referenced in the NCBI Databases (https://www.ncbi.nlm.nih.gov/nlmcatalog/journals)




*National Library of Medicine (NLM)*

2. Enter the journal title in search box. For this example, we are using Missouri Medicine.
3. From the results page, find and click on the title, and scroll to find "Current Indexing Status."

**Missouri medicine**

**Author(s):** **Missouri** State Medical Association
**NLM Title Abbreviation:** Mo Med
**ISO Abbreviation:** Mo Med
**Title(s):** **Missouri medicine**.
**Other Title(s):** MO MED
**Missouri** M.
**Missouri** Med
J. **Missouri** M. Ass.
J. **Missouri** M. Assoc.
**Continues:** **Missouri** State Medical Association. Journal ISSN 0096-7009
**Publication Start Year:** 1953
**Frequency:** Bimonthly, Sept./Oct. 2002-
**Country of Publication:** United States
**Publisher:** St. Louis.
**Latest Publisher:** Jefferson City Mo : **Missouri** State Medical Association
**Description:** v. illus., ports.
**Language:** English
**ISSN:** 0026-6620 (Print)
0026-6620 (Linking)
**Coden:** MIMIA2
**Electronic Links:** http://www.msma.org/**missouri-medicine**-library.html
https://www.ncbi.nlm.nih.gov/pmc/journals/3501/
**In:** MEDLINE: v63n1,Jan. 1966-
PubMed: v63n1,Jan. 1966-
Index medicus
PMC
OLDMEDLINE
**Current Indexing Status:** Currently indexed for MEDLINE.

*National Library of Medicine (NLM)*

### *Indexing Status*

Authors want their research to be discoverable and read by others. A quality journal will be indexed by major bibliographic and citation databases such as MEDLINE®, Elsevier Scopus and EMBASE, Clarivate Analytics Web of Science, Cumulative Index for Allied and Health Literature (CINAHL), and others. MEDLINE® is produced by the National Library of Medicine (NLM) and has rigorous scientific and editorial criteria for journals selected for indexing in MEDLINE®. Among librarians at our institution, Bernard Becker Medical Library, MEDLINE® indexed journals are considered to be the premier journals in the biomedicine field and many authors rely on MEDLINE indexing status as a strong indicator of a

quality journal. In addition, MEDLINE® is a freely available citation database with no subscription required so any author can check for indexing status. As of July 2019, there are 4,995 journals currently indexed by MEDLINE® (Figure 1).

However, some journals claim to be indexed by PubMed® which can be confusing as MEDLINE® citations are found in PubMed® along with citations to full-text articles from PubMed Central® (PMC). PubMed®, MEDLINE®, and PMC® are separate entities with different purposes.

- PubMed® is a resource that aggregates citations from MEDLINE®, PMC®, and other resources from the NCBI Bookshelf.
- PMC® is a free archive of full-text journal articles.
- MEDLINE® is a journal citation database from the National Library of Medicine (NLM).

The single web interface of PubMed® blurs these distinctions, leading to confusion for authors and in some cases, publishers. Journals that claim to be indexed in PubMed® or Google Scholar are cause for concern. When it comes to selecting a journal, we encourage authors to verify the indexing status of a journal using a bibliographic and citation database rather than relying on the journal website, or check with a librarian affiliated with your institution or a local public library.

### *Impact Factor Scores*

Authors often use various journal impact factor scores as criteria for selecting a journal. The Journal Citation Reports Journal (JCR) Impact Factor score was developed in the early 1960s for selection of journals in the Web of Science citation database and as an acquisitions tool for libraries.[11] The JCR Impact Factor score evolved over the years to be associated with identifying "high impact" journals for publication.[12] Other journal impact scores have been launched recently, including the Eigenfactor, introduced in 2008, and CiteScore, launched in 2016. Impact factor scores are calculated for indexed journals in the Web of Science and Scopus databases, and broadly, the calculations are based on the number of citations within a specific timeframe garnered by publications from journals. Some journals often note impact factor scores from sources such as a directory or a catalog which do not contain citation data. Authors should be wary of vague scores touted from non-citation data sources. A more holistic approach in selecting a journal is recommended instead of relying on impact factor scores. Per Ioannidis and Thombs, "Authors should pick target journals based on relevance and scientific rigor and quality, not spurious impact factors."[13]

### *Journal Operations*

Journal operations include archival practices for articles using platforms such as PORTICO (https://www.portico.org/) or JSTOR (https://www.jstor.org/), whether a Digital Object Identifier (DOI) is assigned to articles or an International Standard Serial Number (ISSN) is assigned to the journal, and the publication schedule. An irregular publication schedule, excessive advertising, and missing or sporadic issues are indicative of unstable journal management. The aim and scope, editorial board, instructions for authors, and journal contact information should be available and easy to find.

### *Invitation to Publish a Manuscript or Submit an Abstract to a Conference*

We are aware of many email solicitations for journal publication or invitations to submit an abstract for a conference, and in some cases, including invitations to speak at conferences. These emails are usually generic in nature and contain stilted or archaic language. Unrealistic promises are made such as acceptance of publication within hours and publication within days. Some emails include phrases such as "let us know how much you can afford towards the article processing charges." Table 1. Names, postal addresses and email addresses are taken from publication records found online in freely available databases and for some, the subject line of the emails match verbatim the title of a funded NIH award and the full Principal Investigator's name as noted in NIH RePORTER, (https://projectreporter.nih.gov/reporter.cfma), a freely available resource. There are instances where authors are invited to submit a publication in a journal such as those published by Annual Reviews and these invitations are usually sent by a known colleague in your field of research. If it sounds too good to be true, it usually is.

Our institution has even warned that emails from conferences or journals may be potential phishing attempts. If you are interested in a specific conference or journal but are unsure if it is genuine, apply commonly recommended techniques for handling suspicious email: don't click on any links in the email itself, rather type in the address for the conference or journal website on your browser. Then use the criteria described above to determine if the event or journal is credible.

## Conclusion

Publishing in journals that are not reputable can diminish the credibility of your research, limit your career, and may result in little or no dissemination and uptake. When selecting a journal for your publication, a good

**Table 1. Email Solicitation Warning Signs**

- Archaic salutation
- Hyperbolic language in email
- Poor grammar or misspellings
- Excessive use of exclamation marks
- Promises of swift review or immediate conference abstract acceptance
- Journal aim and scope and conference topic is not germane to your area of research
- The publisher or conference organizer is unfamiliar
- Journal or conference title is similar to an established journal or conference
- The publisher icon/logo is similar to an established journal
- No credentials for the editor, editorial staff, and/or editorial board members
- Indexing status for the journal is noted as PubMed® or Google Scholar or a directory
- Vague impact score for the journal or claims that the journal is high impact
- Inappropriate images or ads/animations on website
- Inconsistent publication or conference history/schedule
- No ISSN for the journal
- No DOI for the publications
- Request for fees upfront or waiver of all fees

starting point are the journals that you, your colleagues, and mentors use for research and clinical care. The next step is to review publications in the journal you are considering to assess the scientific rigor and editorial quality of the publications. Transparency from the journal as to its aim and scope, the editorial board, indexing status, the peer review process, reputation, and policies for authors are among the key indicators of quality journals. These criteria can help identify quality journals suitable for publication. Two resources with additional guidance we recommend are: Think. Check. Submit. (https://thinkchecksubmit.org/) and Principles of Transparency and Best Practice in Scholarly Publishing from the Open Access Scholarly Publishers Association (https://oaspa.org/principles-of-transparency-and-best-practice-in-scholarly-publishing/). Another option for authors is to consult with librarians affiliated with your institution or a local public library. Librarians are well-suited to provide guidance in helping authors with selecting quality journals to consider for publication. While it involves some effort, performing due diligence in your evaluation of the integrity, history, practices, and reputation of a journal before submitting a manuscript will help ensure that your work gets the readership it deserves.

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## Disclosure

Cathy C. Sarli is a reviewer for the NIH National Library of Medicine PubMed Central (PMC) Journal Review Program. The views expressed here are personal and do not necessarily reflect the views of the National Library of Medicine, the National Institutes of Health, or the U.S. Department of Health and Human Services.

## Acknowledgment

The authors thank Robert Engeszer and Mychal Voorhees for their review of the work.

**MM**

*Hear Me Out*

# Cochlear Implantation Within an Increasingly Connected and Cosmopolitan World

*by Joshua M. Sappington, MD*

**Studies have demonstrated that most patients who are candidates do better with cochlear implantation than they do prior to implantation.**

Our world is currently more connected than it has previously ever been throughout history. Today thanks to the internet individuals often have the world at their fingertips. At any given moment one is able to use a phone, tablet, or computer to access information and experiences from around the world. Our world has become so wired that many often will go to great lengths to "unplug." A significant part of this interconnected experience and sharing is due to social media. Thanks to applications such as Facebook, Instagram, YouTube, and others one is able to share thoughts, pictures, and videos from their life quickly. This instant ability to post and share has impacted our lives and the world around us. We are now able to perform a quick search and see someone's thoughts, feelings, and experiences nearly instantly from the other side of the world. This access has the potential to broaden one's life experiences due to someone or something that they may never have had experience with. Conversely, it has been seen and well documented that thanks to the disconnect and anonymity of being at a keyboard this can bring out overly critical, toxic, and even hateful speech.[1] This is especially true when there are shared thoughts and or moments that may be controversial.


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## Cochlear Implants

Cochlear implantation has been and will continue to be a revolutionary aspect of modern medicine. Over the course of 50 years cochlear implants have evolved from experimental to increasingly common place with improved outcomes and expanded indications.[2,3,4,5,6] These implants are the first and to this day the only bionic sense organ. If someone loses the ability to see, to smell, taste, or feel there is unfortunately no medical replacement for these senses. If someone loses the ability to hear and is unable to utilize hearing aids due to the degree of their hearing loss then cochlear implantation offers the ability to restore hearing for these patients. As one can imagine the inability to hear can and does have a massive impact on effected patients. Hearing loss poses not only a significant social burden for effected patients but also a financial one.

The World Health Organization estimates that unaddressed hearing loss poses an annual global

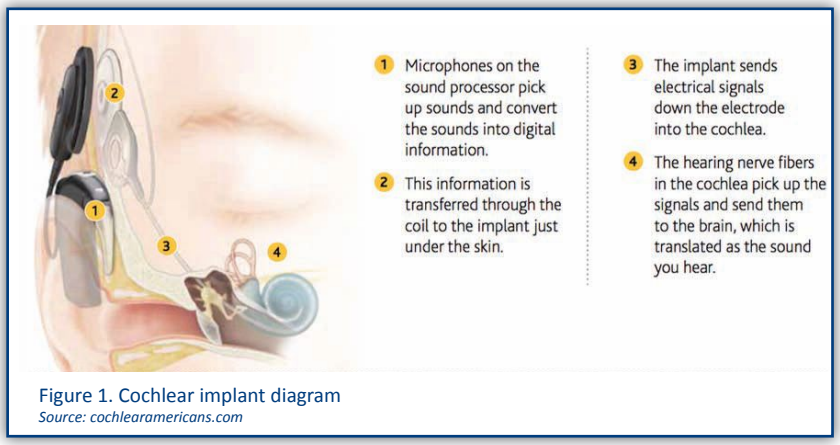


Figure 1. Cochlear implant diagram
*Source: cochlearamericans.com*

Figure 2. Patient with cochlear implant

cost of 750 billion U.S. dollars.[7] Within the United States disabling hearing loss (more than 35 dB loss) costs 133 billion per year.[8] Within the EU this same degree of hearing loss is believed to cost 216 billion per year within Europe.[8] Additionally, there are significant costs to patients. As for many they pay a significant percentage if not all of the cost of hearing aids. Thankfully for patients who are cochlear implant candidates insurance can cover the cost of the implant, surgery, rehabilitation, and upgrades. Recent studies have demonstrated that hearing loss has a significant association with educational achievement. Hearing loss has been shown to be independently associated with economic hardship as well as low income and employment issues' including unemployment and underemployment even when education and demographic factors are accounted for.[9]

Determination of cochlear implant candidacy involves advanced audiologic testing to determine if patients are indeed candidates (Figures 1 and 2). These testing sessions take several hours and are absolutely critical to determine if a patient would benefit from implantation. These are patients who have lost the benefit of hearing amplification and have significant difficulty communicating. Affected patients can be children with the inability to acquire language and progress through their educational tract or adults who have increasing issues with maintaining employment and become increasingly isolated. Following determination of candidacy, a discussion of the risks, benefits, and expectations of cochlear implantation are discussed in detail with the patient or family. The most important aspect for patients and family members that is discussed is that cochlear implantation is not a quick fix. It is learning to hear again in a different manner, and as with any relearning process there is an associated rehabilitation. This is clearly discussed with patients and families prior to any procedure. It truly takes a village and patients and families invest in the process to obtain the best outcome.

As one can imagine over the years there has been significant conversation regarding cochlear implantation. This is natural for any thing that is revolutionary, however; with regards to cochlear implants there is an additional layer to this discussion. Without the innovation of cochlear implantation patients both children and adults would potentially need to learn sign language in order to communicate. This has lead some to have issues and concerns with regards to cochlear implantation. These concerns have ranged from minor to much greater. There have been some who have equated cochlear implantation to extermination of a culture, specifically some in the Deaf culture. Much has been written about this and the consensus has been that the greater good and well-being for a patient whether child or adult is more important than one particular groups interests.[10]

## Controversy on Social Media

The advent of social media has allowed for individual with a common interest or experience to connect regardless of where they live. This has allowed for cochlear implant recipients and their families to connect and share their experiences. For many this is a positive which allows them to share the highs, lows, and every day of their journey. Something that has become increasingly notable on social media

are the videos of patients having their cochlear implant activated. For many patients and family members this moment in their lives that is comprised of a myriad of emotions. Everything from excitement, anxiety, joy, and disappointment are emotions that patients may experience. For some it can be a very personal moment while for others they wish to share it with the world. There has been some criticism that posting videos such as this romanticizes cochlear implantation. I disagree; it is someone's personal experience, and if they choose to share that aspect in their journey, they should be able to. One should be able to share their experience as long as it is respectful. If a patient or family member wants to share a moment in their cochlear implant journey they should. If they were to be subsidized by a hospital, care team, or corporation to promote the technology that would be another matter. The larger issue is the motivations and designs of a those who are critical of sharing these moments. Sharing a video of an activation session and/or programming sessions is not sensationalizing or sugarcoating an experience.

If we are to discuss this objectively, we have to analyze and discuss what the outcome is for patients. For the vast majority of patients both pediatric and adult they do better with cochlear implantation than without. For children cochlear implantation has the potential to allow them to obtain a mainstream education. For adults, cochlear implants have been shown to improve quality of life. This includes the costs associated with the device, surgery and aural rehabilitation. Additionally, I have seen first-hand the improvement that cochlear implantation can make for a patient within my family. I have a family member who is post lingually deafened and underwent cochlear implantation. The severity of his hearing loss forced him to retire earlier than he wanted because he was not able to perform his profession. This implantation was not an immediate quick fix but he has done very well with his implants. For years I could not speak with him on the telephone and he was severely limited with regards to his social activities. His cochlear implants have truly given his life and family back to him which has been amazing to see and experience with him.

## Ultimately, It's About Improving Quality of Life

Ultimately, cochlear implantation has been a revelation within modern medicine and has had a profound impact for patients, their family, friends and social community. Studies have demonstrated that most deaf patients do better with cochlear implantation than they do prior to implantation. The decision to proceed with implantation is an intensely personal decision made by patients and family for those who lack decision making capacity. Social media how allowed individuals to share their experience and their journey as they rehabilitate their hearing. Ultimately, that shared experience is something that should be respected by all. The key is that it needs to be honest and not demeaning or hateful. There is a responsibility for all to be respectful of others views even if one does not agree with it. Any discussions need to be based of fact and not emotions or fear. We are all entitled to an opinion however respect is paramount as our opinions interact. So let individuals and families share their unique experience and journey with friends, family and if they choose publicly. One can always choose to abstain from clicking play if it's something one doesn't care to view.

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MM

*Hear Me Out*

# Hearing Each Other for the First Time: The Implications of Cochlear Implant Activation

*by Amelia Cooper*

**While many people object to cochlear implant activation videos on the basis that they are sensationalizing and reductive, others oppose them for being oppressive and offensive.**

On January 5, 2007, YouTuber Kwilinski uploaded a video of a deaf six-month-old boy reacting to the activation of his cochlear implant device. Others began to post similar videos. With titles like "Baby Aida Reacts to Hearing Her Parents' Voices for the First Time" and "Hearing My Husband Say I Love You For the First Time," cochlear implant activation videos became an ongoing viral trend. The most popular, "29-Year-Old and Hearing Myself for the First Time!" was uploaded by Churman[1] in 2011 and amassed 27 million views and 57,000 comments. The video received 260,000 likes and was praised for being "heartwarming" and "uplifting." It also elicited hundreds of furious comments and 4,000 dislikes. Many hearing people might wonder who would criticize such an inspirational video?

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## Sensationalizing Cochlear Implants

Cochlear implant surgery is controversial, at least in the Deaf community. Cochlear implants are not a "miracle cure" for deafness. The YouTube "comments sections" of cochlear implant activation videos have become a forum for the controversy. The postings are often bitter, demeaning, and often anonymously delivered. After reviewing these comments, I believe that there are valid arguments on both sides of the debate. Arriving at an acceptable compromise may be possible if we endeavor to better understand each opposing viewpoints.

In her 2014 article "Why You Shouldn't Share Those Emotional 'Deaf Person Hears for the First Time' Videos," Lilit Marcus,[2] a CODA (Child of Deaf Adults) and member of the Deaf activist community, expresses her disdain for the YouTube trend of cochlear implant activation videos. She claims that they sensationalize and romanticize cochlear implants while whitewashing the struggles recipients face. Although Marcus has no problem with those who make the personal medical decision to receive cochlear implants, she does have a problem with "the maudlin videos produced out of someone's intense, private moment that are then taken out of context and broadcast around the world." The author further notes "how the viewer never learns how the individual came to the decision about their implant, and which factors they took into account."[2]

She believes the videos sugarcoat the shock and horror many recipients experience. When the implant is first activated, some recipients often sob convulsively in a fearful response to the sudden flood of sensory inputs. This sort of somber reaction is seldom seen online. In the viral video "My Cochlear Implant Activation!" Ann Swartz commented, "Deaf children always seem to smile when they hear for the first time."[3] Titles such as "Hearing My Husband Say I Love You for the First Time!" may downplay the recipient's

recovery while glamorizing the activation experience, as they suggest that recipients can process and comprehend speech immediately. It takes months, sometimes even years, before cochlear implants can function fully. The brain needs time to "rewire itself before it can even comprehend the new sensory input."[4] Recipients must then undergo extensive speech therapy to learn the meaning of all the new sounds.

The most erroneous message the videos propagate is that cochlear implants fully transform deaf individuals into hearing ones. With present technology cochlear implants are a tool, not a cure. The most successful cochlear surgeries never restore full, natural hearing. Many recipients struggle to distinguish sounds, particularly in environments with a lot of background noise.[5] The comments on many of these videos embrace the fallacy that cochlear implants are a one-size-fits-all solution.

This misconception may harm pediatric recipients. Some parents of children with cochlear implants believe their child is "hearing" like them, so they do not teach their child American Sign Language (ASL). Not learning sign language may delay their child's language acquisition.[6] According to the National Association of the Deaf (NAD), cochlear implants do not provide recipients with "clear and unambiguous access" to linguistic input in the same way that sign language does. For young children learning their primary language, "reliance on only spoken language input via cochlear implants may result in linguistic deprivation if sign language is excluded from [their] environment."[7]

## Implications of Cochlear Implants for the Deaf Community

While many people object to cochlear implant activation videos on the basis that they are sensationalizing and reductive, others oppose them for being oppressive and offensive. For these critics, deafness is not defined by the lack of ability to hear, but rather, by a distinct cultural identity of which they are proud. They believe the word "deaf" with a lowercase "d" refers to "the audiologic lack of hearing," while the word "Deaf" with an uppercase "D" refers to a cultural identity.[8] Members of the Deaf community share essential ingredients of culture: a language, a history, institutions such as schools and clubs, sports, art, and movies. Due to these shared establishments, many Deaf individuals primarily socialize among themselves and "have limited social interactions with people from the majority culture."[8] Ninety-five percent of Deaf marriages involve two deaf partners.[8] Because their deafness allows them to be a member of this supportive community, many Deaf people report that they do not want the ability to hear.[9] According to the NAD, "Deaf people like being Deaf, want to be Deaf, and are proud of their Deafness".[7]

Many Deaf culturalists are deeply offended by what they perceive to be the inherently negative implication of cochlear implants: deafness is a medical disability that should be cured rather than a cultural identity that should be celebrated and respected. The comments sections of cochlear implant activation videos are often flooded by angry remarks about how Deaf people do not need nor want to be "fixed." On a YouTube video titled, "Deaf People Hearing Sound for the First Time [Compilation]," which amassed 6.6 million views, a commenter with the username "Tzion" passionately rebuked, "Can someone say inspiration porn??? We don't need to be fixed so it's easier on you hearing people with a thing that causes so many issues. How about actually learning to communicate with us?[10]

Not only do many Deaf culturalists find the assumption that they need to be "fixed" or "cured" insulting, some contend that cochlear implant technology threatens to destroy their culture. Because 90 percent of deaf children have hearing parents, cultural transmission of Deaf culture does not occur within families, but rather, through Deaf institutions.[11] As cochlear implants will inevitably lead to a decline in the number of ASL speakers, there is a fear that fewer people will participate in Deaf institutions, and eventually Deaf culture will disappear.

Believing that cochlear implant technology deprives the Deaf community of members and threatens Deaf culture, Deaf culturalists like Rob Sparrow feel that cochlear implants represent a form of minority oppression.[11] Some have even gone so far as to liken the act of "curing" deafness to genocide. These individuals believe that cochlear implant technology and Deaf culture cannot coexist. In ASL, the sign for cochlear implant is a "two-fingered stab to the back of the neck, indicating a 'vampire' in the cochlea."[9]

## Countering the Deaf Opposition to Cochlear Implants

The Deaf opposition to cochlear implants faces heavy and often brutal criticism, especially online. According to ASL, Saunders,[6] online discourse has repeatedly accused Deaf culturalists of "victimizing themselves and creating trouble." Yet the Deaf community is vastly underrepresented on social media compared to other cultural minorities and causes. Unlike written English, the order of words in ASL is dictated by the most efficient means of performing the appropriate hand gestures, and thus individuals whose primary language is ASL usually struggle to express themselves online. Discussions about issues relevant to the Deaf community often are dominated by those "opposing the Deaf cultural viewpoint."[6] Saunders terms the online bullying of the Deaf

community as "cyberaudism."[6] In the comments section of a cochlear implant activation video with 2,500 dislikes, "Animegirl17" wrote, "Whoever [is] disliking these videos need to drink bleach."[10] In response to a commenter who insisted deafness was a cultural identity, "AnomalyINC" wrote, "Being deaf is a handicap. So is being blind. Or mute. Or paralyzed. Or really, really stupid." "Relaxed Cease" commented, "You suck, your opinion is wrong and I hope that you (expletive) off from videos of happy endings."[12]

Since its invention in 1982, many people have seen the technology as an important advancement that creates opportunities for Deaf individuals. An article from 1988 contains an interview in which cochlear implant recipient Bill Boyle was asked if cochlear implants took away his Deaf pride, to which Boyle responded, "I feel the implant enhances my pride. I am proud to be overcoming what was considered a severe handicap, proud to be part of the community as a whole, not to a club of narrow-minded people."[9] Twenty years later, Boyle's description of cochlear implant protestors as a "club of narrow-minded people" still reflects a sentiment held by many critics: the Deaf opposition to cochlear implants is tribalistic, militant, and values the interests of a culture over the interests of an individual.

In a 2017 cochlear implant activation video, "Cao Cao" commented, "Being proud of a disability is stupid. Serves no purpose and it's not a culture. It's a cult."[10] Although this comment is hostile, its comparison of the Deaf community to a cult is not invalid. Just as cults have been known to shun former members,[13] many cochlear implant recipients report that they no longer feel welcome by their Deaf friends after surgery, and so they feel they must leave a community they have been a part of their entire lives.[2] The belief the government is actively scheming to destroy deaf culture and even commits "genocide" by funding cochlear implant research reflects the "us versus them" mentality for which cults are notorious.[11, 13]

Another longstanding argument is that it is immoral and even selfish for parents of deaf children to reject the use of cochlear implants simply because they want to preserve a culture. In the aforementioned 1988 interview, Melissa Chaikof, the mother of a cochlear implant recipient, reports, "In obtaining implants for our daughter, we did not have the ulterior motive of breaking down Deaf society." Chaikof goes on to say that her "concern for [her] daughters' future is far greater than for the future of Deaf society."[9] Similarly, in response to a cochlear implant activation video of an eight-month old boy from 2008, "Sallyallie89" commented: "What person would choose to be deaf? I bet if you ask this kid in 10 years if he is happy for what his parents did, he will tell you that he is extremely happy [...] Sorry, but if my kid is sick, I'm treating them. I'm the mother. It's what parents do. Take care of your child."

The question of whether we should preserve a culture at the expense of the individual— and of scientific progress—is one that extends far beyond the Deaf community. The world is becoming increasingly monolingual. Ninety-four percent of the world's population speaks only six percent of the world's languages. It is estimated that by the year 2100, 90 percent of the world's languages will cease to exist.[14] While many members of linguistic minorities fear the loss of self-identity as their respective languages and cultures are assimilated by the mainstream, others argue that language death is inevitable and even creates new opportunities. In his controversial article "Let Them Die," broadcaster and author Kenan Malik advocates for the existence of a universal language, claiming that "contact across barriers of language and culture allows us to expand our own horizons and become more universal in outlook."[15]

According to bioethicist Wildes, "The controversies in bioethics illustrate the challenges of addressing moral issues in a morally pluralistic society."[16] We cannot categorize the perspectives on the cochlear implant controversy as ethically "right" or "wrong." We can, however, accept moral ambiguity and cultivate open-mindedness and empathy.

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**MM**

# From Suffrage to the Senate: Expanding Inclusion in Women's Rights to Achieve Women's Health Equality

*by Frances Grimstad, MD*

Women's rights movements have evolved significantly since the early 20th century. From the right to vote to basic reproductive rights, women acting together have caused major social change, which has improved women's health equality (WHE).

While we applaud our progress to date, we also acknowledge that these efforts have focused on the priorities of women with socioeconomic privilege. And while all women have benefited from this progress, it is also clear that the women's movement agenda must be broadened to include women who don't come with all of the advantages.

Leading and speaking for the women's movement has become a prominent issue. As the US populace continues to gain understanding of the colorful quilt that comprise all women's experiences, we can no longer allow the movement's focus to be solely that of privileged (and predominately white) women.

Women represent 51% of the US population, but we are not a homogenous group.[1] In a recent article of Missouri Medicine, female genital mutilation (FGM) was brought up as a call to action for providers to recognize this injustice inflicted upon women, to support survivors and to prevent further FGM. Unfortunately, FGM is just one of many WHE issues. If our goal is sustainable WHE, we must consider the many health challenges confronting women who are not in the spotlight, and ensure those so afflicted are aggressively engaged in the leadership of a diverse and inclusive movement.

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As providers we have a unique exposure to the challenges faced by our female patients. We see first-hand how health issues can limit their ability to lead full lives and how social inequalities directly impact health inequality.[2] We have an opportunity to advocate for their voices. Our goal is to be their ally, not just their physician.

So how do we advocate for and alongside our marginalized female patients to achieve health equality? How do we actively work to overcome the diverse injustices faced by women infrequently represented on the covers of magazines, or the pulpits of change? Our current national women's rights leaders have been effective advocates for protected maternity leave, equal pay and access to contraception – all of which are vitally important to WHE. But it's important to remember the other disparities that affect large portions of the female populace.

While an exhaustive list of the unheard constituencies is beyond the scope of this article, there are several groups we can start to help today. How? By engaging with them in our own clinical spaces and in local public advocacy. We need to understand not only on the experiences they face, but also how we contribute to perpetuating these inequalities. Who are some of these groups?

## Women of Color

Black women are three to four times more likely to die from a pregnancy related complication than white women.[3] Even when controlling for economic status, infants born to black women in the middle class are more likely to die prior to their first birthday compared to infants born to white women in poverty with less than a high school education.[4] While baby friendly hospitals and lactation suites at work advance our WHE agenda, we must also institute programs to address racial disparities and to support black women in accessing safe and affordable care. It also means supporting programs that help health care providers address their own unconscious bias so they can help build unbiased systems of care.

Black women are leaders of the civil rights movement.
*Source: Johnny Silvercloud, Flickr*

## Undocumented Women

WHE means ensuring that undocumented women have protected access to health care resources, regardless of documentation status (including signage and verbal support that documentation will not impact their access to care).[5] Undocumented women are at increased risk of sexual assault and intimate partner violence, human trafficking, poverty, and denial of health care.[6,7] Fear of deportation or discrimination further limits their desire to access existing resources. WHE means providing interpretations services and education for staff on cultural competency and trauma informed care, in order to help create welcoming, safe clinical spaces that include incorporating understanding of the journeys they have made.

## Gender and Sexual Minorities

Included in these welcoming spaces should be an acknowledgement that people who are impacted by women's rights and WHE, have diversity of gender and sexuality. This means that conversations about WHE should include discussions about disparities faced by all persons who are gender and sexual minorities including lesbian, bisexual, transgender, and intersex persons. WHE means understanding that reproductive access is not just sought by persons who identify as women, but by transgender and intersex persons as well. [8,9] It means understanding as clinicians that not every woman has a uterus and not every person with a uterus identifies as a woman.[10,11] WHE means removing provider bias regarding perceptions surrounding our patient's gender identity, sexuality, or anatomy. It means advocating for inclusive insurance coverage, posting nondiscrimination policies and adapting our clinic aesthetic, and changing workflow and medical records to be inclusive of gender and sexual diversity patients.

## Sex Workers

Another population to be considered is one that for generations has been pushed to the background of conversations: sex workers. Sex workers predominately identify as women, and are disproportionately the targets of violence, sexual assault, and murder.[12–14] Because of the US criminalization policies on sex work, these individuals are often reticent to work with the legal system. Consequently they are often reticent to disclose their employment status to health care personnel due to fear of mistreatment, including harassment, discrimination and refusal of services.[15,16] WHE means providing sex workers with equal access to care, creating safe spaces for open conversations about sex, and supporting their voices in legislation targeted at their protection.[15]

## Survivors of Violence

One cannot address sex workers without also speaking about survivors of violence. The "me too" movement, started by Tanara Burke, has educated the nation on the sweeping effect sexual violence has on our citizens. Despite this, the movement has evolved into a discussion highlighting the powerful and famous women who bravely have come forward. It has seemingly left in the shadows the women for which it was initially created: disenfranchised women, especially, women of color and women experiencing poverty.

Discussing violence against women means acknowledging that the same populations disproportionately targeted by sexual violence are also at higher risk for violence in general, including intimate partner violence, gun violence, stalking and homicide.[17,18] Providers should have resources ready to help patients exit unsafe situations, and utilize harm reduction and trauma informed models of care to decrease re-traumatization in the clinical setting.[19]

## Women with Disabilities

Another critical constituency are women with mental and physical disabilities. WHE needs to be accessible to all persons of varying abilities. Women with disabilities need to be included in the conversation when creating health care spaces, workflows and competency trainings. Supporting this diverse part of our community means thinking about how individuals with sensory processing forms of autism might not feel supported in loud, crowded spaces, about how your clinic is laid out to be easily accessible in persons with ambulatory disabilities. WHE means not centering their health care solely on their disability (e.g. persons with disabilities reproductive needs have often been placed on the backburner by clinical providers).[20] Women with disabilities are also at higher risk for abuse, including sexual abuse, in the home and in hospital care settings.[21] Assumptions should not always be made that caretakers are safe guardians.

## Women Who Are Incarcerated

Perhaps the least engaged women are those who are incarcerated. While only ten percent of persons currently incarcerated identify as female, over half of them have experienced sexual violence prior to incarceration, and one in five to one in six are sexually assaulted while incarcerated.[22,23] Over two thirds are incarcerated for nonviolent offenses, and the majority identify as primary care takers for dependents. WHE means not only supporting decriminalization of many of these offenses but also ensuring women who are incarcerated are receiving appropriate health care and safe access to providers when they disclose prison abuse or assault.[24] This includes supporting hiring practices for persons with a history of incarceration since women who were formerly incarcerated are also more likely to end up in poverty and unemployed after release.[25]

## Women Who Are Poor

Overarching all of the above is the reality of poverty. Over half the individuals living in poverty are women. Roughly one in four black and Hispanic women live in poverty, compared to one in nine to ten white women. All of these rates are higher than men of the same race.[26]

Figure 1. Examples of women-led local, state and national organizations addressing above disparities

**Autism Women and Nonbinary Network** – Provides community, support, and resources for Autistic women, girls, nonbinary people, and all others of marginalized genders (USA)
https://awnnetwork.org/

**Black Mamas Matter Alliance** – Alliance of organizations and leaders advocating for black women's health (USA)
https://blackmamasmatter.org/

**Migrant and Immigrant Community Action Project** – Provides outreach and legal services to support the voice and advocate for immigrant communities. (St. Louis)
http://www.mica-project.org/

**National Organization for Women: Missouri Chapter** – Cross-sectional advocacy organization for women's rights issues (Missouri)
https://missouri-now.org/

**Ruth Ellis Center** – Provides trauma-informed services for homeless, runaway and at-risk lesbian, gay, bi-attractional, transgender and questioning (LGBTQ) youth and young adults of color. (St. Louis)
http://www.ruthelliscenter.org/

**Rung** – Supports women in sustainable, holistic, economic endeavors to escape poverty (St. Louis)
https://rungforwomen.org/

**Sex Worker's Outreach Project** –Advocates for the fundamental human rights of sex workers and focuses on ending violence and stigma through education, community building, and advocacy. (USA)
https://swopusa.org/about-us/

**Tegan and Sara Foundation** – Advocates for health, economic justice and representation for LGBTQ girls and women (USA)
https://www.teganandsarafoundation.org/

**The Justice Project of Kansas City** – Provides justice and social systems advocacy and navigation for women in poverty who may suffer from such challenges as homelessness, discrimination, addiction, domestic violence and sexual exploitation. (Kansas City)
http://justiceprojectkc.org/

**Transgender Intersex Justice Project** – Advocates for transgender, gender variant and intersex rights, inside and outside of incarceration. (USA)
http://www.tgijp.org/

**Uzazi Village** – Addresses maternal and infant health disparities in the urban core, including but not limited to African American women (Kansas City)
http://www.uzazivillage.org/

Wages directly contribute to health quality as part of the social determinants of health.[27,28] By supporting living wage policies, providers can directly engage in improving their patients' quality of life. Financial stability contributes to higher rates of medication continuity, follow up visit compliance, and decreased rates of utilization of emergency rooms for primary health care.[29–31] As providers who believe in WHE, we need to recognize the challenges often linked

to poverty, such as accommodating those who are late due to public transit limitations and offering social support resources for patients seeking stable housing, access to food and employment.

## So What Can We Do?

Supporting WHE means not only listening to women's voices, but also thinking about how to promote those voices into leadership roles. As providers, we can do so much. Show up to events sponsored by the groups listed above. Support organizations run by these women (Figure 1). Bring in speakers to hear their experiences as our patients, to help us improve our clinical care. A few simple steps but ones that demonstrate our understanding and commitment.

In addition, think about who is presenting you with information on WHE, on the struggles of these constituents. I am a white, economically privileged female. I cannot speak for women whose life experiences are so different from my own. This piece is not a desire to usurp their voices. Rather it's a desire to rally those providers with my background to be allies to these under-represented constituencies. To actively work to bring their voices to the forefront.

Nor is it the intention of this piece to beat up the leadership of today's women's movement. Their accomplishments resurrecting the movement have been critical to reenergizing discussions about key topics like WHE. But there is much work to be done. Broadening the movement's leadership to include the constituencies discussed above will not be easy, and it will not happen quickly. Becoming active supporters of this process is a critical first step. One we are uniquely positioned to take.

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# The Caduceus vs. Staff of Aesculapius - One Snake or Two?

*by George Bohigian MD*

There is much confusion of the true symbol of medicine. The single staff with one snake-entwined is the current American Medical Association logo. The history of this ancient symbol with a heritage stretching over two millennia is shrouded in the fog of history.[1] Many physicians as well as the public are unaware there are two distinct symbols commonly used which have two different origins. For example in a 2014 survey in India revealed that only six percent of physicians knew that the Staff of Aesculapius was the true symbol of medicine.[2]

Aesculapius was the god of medicine and was the son of Apollo, the god of healing (Figure 1). The Staff of Aesculapius is a rough-hewn branch representing plants and growth entwined by a single snake. Aesculapius was known as the god of medicine. He was killed by his grandfather, Zeus, with a thunderbolt because not enough people were passing onto the underworld due to his healing skills.[3, 4]

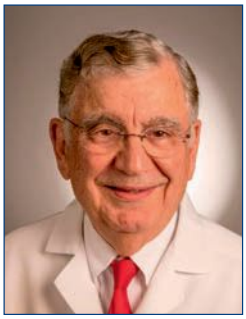
Hermes (Mercury) was the messenger of the gods and known for carrying a staff known as the Caduceus. The caduceus included two snakes topped off with a set of wings. The Caduceus is from the Greek root meaning "herald's wand" and was a badge of diplomatic ambassadors associated with commerce, eloquence, alchemy, thievery, and lying.[5]

The popularity of the caduceus with two snakes is probably attributed to being more aesthetically appealing than the single snake on the Staff of Aesculapius (Figure 2). The symmetry is more balanced than the single snake.[4] The caduceus if often used in medically related industries such as pharmaceuticals and hospital supplies.

The snake is a powerful symbol.[5] The ancients looked on the snake as a symbol of health and healing because it could shed and regenerate its's skin. The snake also produced venoms which killed many parasites in the body. Many patients suffering from sickness such as depression were put into a temple healing rooms containing snakes to shock them out of their stupor.

Hippocrates of Kos was a physician the father of Western Medicine, ca. 450-380 BCE. It was believed that Hippocrates was a direct descendant of Aesculapius. Hopefully, most of you know the Hippocratic Oath begins with the words "I swear by Apollo, the physician, and by Aesculapius…."

The question to ask is how did the caduceus become popular so quickly in the United States? The role of the United States Army Medical Corps (USAMC) is crucial. In 1902, at the suggestion of an assistant surgeon, Captain Frederick Reynolds, a new uniform code was established, and the caduceus became a collar insignia for all personnel in the USAMC. From Captain Reynold's correspondence with the Surgeon General's office, it is apparent that he was unaware of the distinction between the caduceus and Aesculapius. He recommended the combined use of the "cock of Aesculapius" and the caduceus. His statement to the Surgeon General that the Medical Corps of "several foreign powers, notably the English" all displayed the caduceus was



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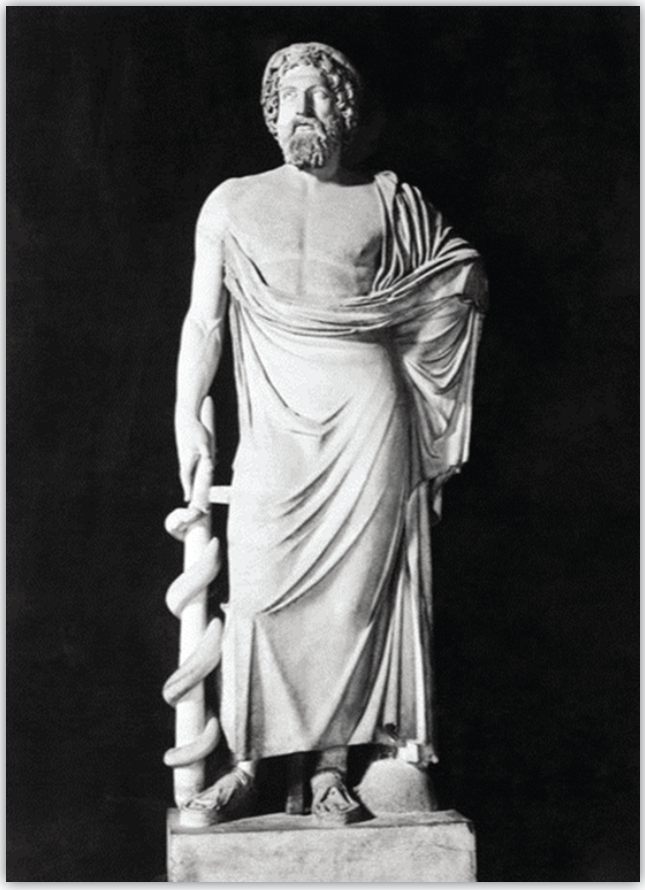

Figure 1. Aesculapius, god of Medicine, was the son of Apollo, The God of Healing.

Figure 2. Two wings and two snakes are the difference in the Caduceus (left) and the Staff of Aesculapius (right).

also erroneous. In fact, no other western medical military service of that time displayed the caduceus; they all used the Aesculapius symbol. Medical Associations in Asia, India, Canada, Great Britain, France, Germany, Africa, and Scandinavia all share the Staff of Aesculapius.

Thus, the adoption of the caduceus by the USAMC seems to have been simply a misunderstanding of classical mythologic iconography.[2] Ironically, this mistake was nearly avoided. In March 1902, when Captain Reynolds initially suggested the switch to the caduceus symbol, the Surgeon General, G.W. Sternberg, dismissed his request outright. However, Captain Reynolds was persistent and, later that year, he sent a second letter to the new Surgeon General, W.H. Forwood; this time, his proposal was approved. Thus, on 17 July 1902, the "caduceus of gold" was adopted as the branch insignia of the USAMC. This mistake did not go entirely unnoticed. In 1917, Lieutenant Colonel McCulloch, the librarian to the Surgeon General, discovered original documents showing that the coat of arms adopted by the USAMEDD a century earlier had displayed the Aesculapius and not the caduceus. McCulloch lamented the error, but did nothing to correct the error.[2] The U.S. Army Medical Corps and the U.S. Navy Medical Corps still use the caduceus with the two snakes. The U.S Air Force Medical Service uses the Staff of Aesculapius with one snake.

In conclusion:

The Staff of Aesculapius has represented medicine since 800 BCE, and most knowledgeable medical authorities support its use as the symbol of medicine.

The *New England Journal of Medicine*, The American College of Physicians, and the World Health Organization use the Staff of Aesculapius.

The Staff of Aesculapius has represented medicine since 800 BCE and most authorities support its use as the symbol of medicine.

The Staff of Aesculapius is the only true symbol of medicine.

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# Correspondence

## Dentistry and Opioids

This letter is in response to the perspective article, "Dentists' Current and Optimal Opioid Prescribing Practices: A Proactive Review," published in the September/October 2019 issue of *Missouri Medicine*.

As a Missouri dentist and the current Missouri Dental Association (MDA) president, I'd like to take the opportunity to inform your readers about what the dental profession, both at the national and state level, is doing to address the opioid epidemic. We're far from solving the opioid crisis, but dentistry has not idly stood by.

For more than a decade, the American Dental Association (ADA) has advocated to keep opioid pain medications from harming dental patients and their families. Nationwide, dentists have written nearly half a million fewer opioid prescriptions over a five-year period.[1] In 2018, the ADA was the first—and remains the only—national health professional organization to agree to mandated limits on opioid prescriptions.

As a state constituent of the ADA, the MDA fully supports the 2018 ADA policy on opioids,[2] one of which includes "*support for statutory limits on opioid dosage and duration of no more than seven days for the treatment of acute pain, consistent with Centers for Disease Control and Prevention evidence-based guidelines*"—limits passed by the 2019 Missouri legislature that the MDA supported.

The ADA has dedicated extensive resources to address the opioid crisis,[3] including creating practical guides for safe prescribing, and providing free online CE and other tools and information for managing dental pain—especially for patients at risk for drug overdose and/or addiction.

The ADA and the MDA urge our dentist members to consider non-steroidal anti-inflammatory drugs (NSAIDs) as a first-line therapy for acute pain management. Research[4] published in the April 2018 *Journal of the American Dental Association (JADA)* indicates NSAIDs, alone or in combination with acetaminophen, are more effective with fewer side effects than opioids for acute pain management.

As to specific points raised in the *Missouri Medicine* article, it begins by noting, "when compared to dentists in England, dentists in the United States prescribe vastly more opioids." While it remains true that U.S. dentists write prescriptions for more opioids than their colleagues in England, dentists are not unique among American providers. *Both* dentists and physicians in the U.S. write many more opioid prescriptions than their counterparts in England. For example, according to a UN report,[5] 99.7 percent of the world's hydrocodone use occurs in the U.S. As a profession, dentistry has been grappling with this issue and making positive recommendations for almost 10 years. Since 2011, many key opioid-related articles in the *JADA* have asked dentists to consider their roles in the crisis and how to address it head on.[6] In short: we as a profession and association are focused on the next steps to take to improve the communities we serve.

The article also discusses what our Missouri legislature is doing. As health care providers in this state, dentists and physicians BOTH must shoulder responsibility related to the epidemic, but so too must our lawmakers. Missouri is the only state in the nation without a statewide Prescription Drug Monitoring Program (PDMP). Establishing the PDMP is a critical next step for our state. MDA policy adopted in 2010 states, "the MDA will provide support for development of a PDMP." Though recent legislative efforts have fallen short, we continue to push for the legislature to act. The perspective article also notes passage of SB 514[7] which included opioid prescription language. The MDA supported appropriate requirements limiting opioid prescriptions and worked specifically with the Missouri Dental Board on its changes to the Dental Practice Act through rules which promulgated limits on opioid controlled substances for treatment of a patient's acute pain.

**Letters to the Editor**

Submissions reflect readers' opinions and may be edited for length.

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With regard to the article's reference to toothaches and emergency departments, Missouri has seen a significant drop in the number of dental-related ED visits from 2014-2018, attributed in part to increased funding for Dental Medicaid, which the MDA always supports legislatively. We hope this translates to care being provided in dental offices, thus decreasing hospitals treating only the symptoms with possible, unnecessary opioid prescriptions.

The opioid epidemic is everybody's business, and there's certainly more work to do. However, we were heartened to see this perspective article proposes many of the actions already undertaken by the dental profession to address the crisis.

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**MM**

## Errata

In the September/October 2019 issue, Vol. 116:5, "Rapidly Developing Large Bilateral Cataracts in a 58-Year-Old Woman After Only 46 Hyperbaric Oxygen Treatments" by John C. Hagan III, MD, James V. Maturo, MD, and John P. Kirby, MD, the age of the patient listed in the article should be 58 as found in the Abstract and in the copy, both on page 396.

## Worldwide Measles Epidemic

I read with interest the manuscript "On the Brink: Why the U.S. is in Danger if Losing Measles Elimination Status" by Mary Anne Jackson and Christopher Harrison in the July/August 2019 issue of Missouri Medicine.[1]

The message delivered was compelling and concerning, but to my view left out an important statistic.

The largest measles outbreak in Europe in 2018 occurred in Ukraine, with more than 54,000 cases and 16 confirmed measles deaths.[2]

Figure 3, from their otherwise excellent manuscript[1] omitted this data. Of course, Ukraine, though located in Europe, is not a member of the European Union.

If Ukraine's measles incidence had been displayed on Figure 3, the red dot would perhaps have been large enough to cover the entire nation of Ukraine.

Being a somewhat regular visitor to Poland, with Poland being located immediately west of Ukraine, being a member of the EU, and being currently impacted by cross-border measles importation, I may be more aware of Ukraine's plight than most MSMA members.

Nonetheless, to omit Ukraine, to omit discussion of it's largely in-immunized population, and to omit the magnitude of Ukraine's current measles burden, I feel a large part of the measles story was inadvertently not communicated.

## References

1. Jackson MA, Harrison C. On the brink: Why the U.S. is in danger of losing its measles elimination status. Missouri Medicine 2019;116:260-265.

2. Measles cases have tripled in Europe, fueled by Ukrainian outbreak. News; Science Magazine; February 12, 2019.

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*Professor of Emergency Medicine*
*Washington University School of Medicine*
*St. Louis, Missouri*

## Worldwide Measles Epidemic Response

We read with interest the communication from Dr. Gaddis who pointed out the extent of measles in Ukraine and areas beyond those we discussed in our article.

We focused on the European Union in part because many Americans tend to think of western Europe as medically sophisticated and having all-inclusive medical care systems. And despite the medical largess of western Europe, measles has again become endemic in several countries.

To respond to Dr. Gaddis' specific concern, we now show a world map of measles (Figure 1). We agree wholeheartedly with his assertion that eastern Europe and parts of the old U.S.S.R. had larger outbreaks with the Ukraine among the biggest players (darker red color). For Ukraine, measles continues to circulate likely related to low immunization rates, expedited by the social and political upheavals in that area. Venezuela also fits this category of immunization interruption due to social and political problems.

A number of medical-resource-limited countries (many African countries, southeast Asian countries, and India) not unexpectedly also had notable measles activity (Figure 1). Finally, New Zealand, and Brazil with reasonable-to-good medical resources joined the list with high measles activity.

So, ongoing measles is multifactorial:

1. Some countries have limited medical resources.

2. Other countries have disruptions in their social and medical networks, so immunizations are neglected.

3. Some affluent and socially stable countries have population subsets who refuse or delay vaccines and thus establish pockets of unimmunized persons where measles can flourish.

The real message of our story: There is likely no country to which one can travel that one can confidently label as truly without any risk of potential measles exposure. So, clinicians should be aware that there are few measles-safe zones and when seeing patients who plan international travel, ensure that measles vaccination is provided (including an accelerated vaccine for infants ≤12 months). This definitely extends to those healthcare workers who are internationally traveling for clinical or academic missions.

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*MSMA member since 2019*
*Interim Dean, University of Missouri - Kansas City*

*Christopher Harrison, MD*
*Infectious Diseases and Pediatrics*
*Children's Mercy Kansas City*

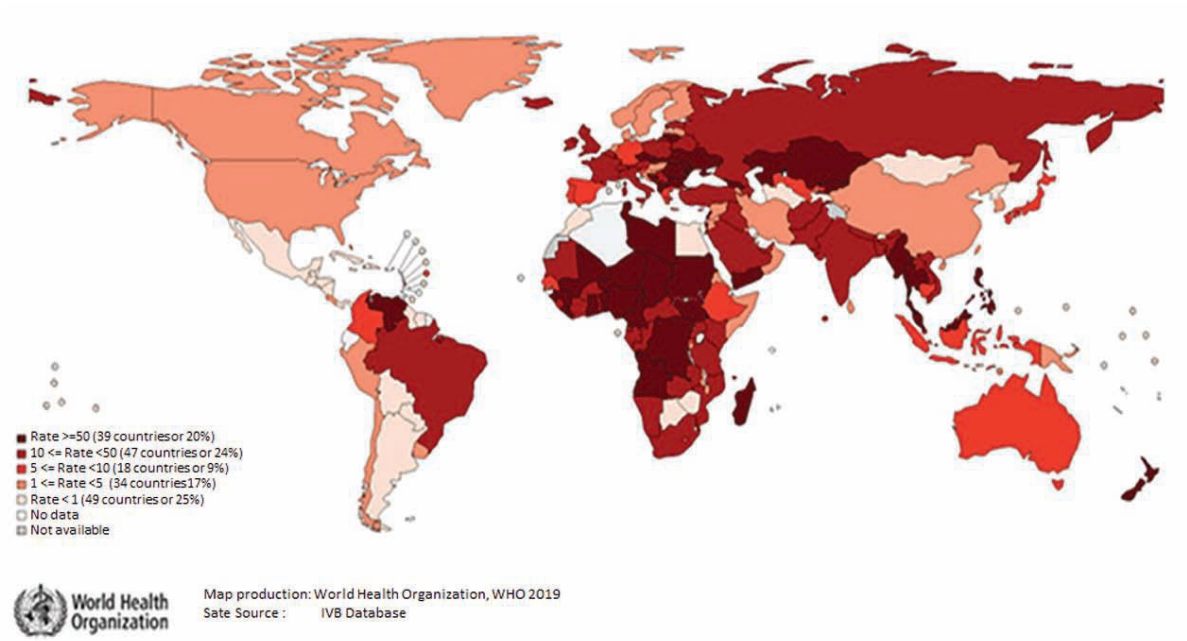



Figure 1. World map of measles activity as of the summer of 2019
From January 1 through July 31 2019, 182 countries reported 364,808 measles cases to WHO. The Democratic Republic of Congo, Ukraine, and Madagascar had the largest 2019 outbreaks (Madagascar rate declining lately due to nationwide vaccination campaign.) Other countries with large outbreaks, in alphabetic order, are: Angola, Cameroon, Chad, Kazakhstan, Nigeria, Philippines, South Sudan, Sudan, and Thailand.
*WHO source: https://www.undispatch.com/map-of-the-day-measles-outbreaks-around-the-world/*

**MM**

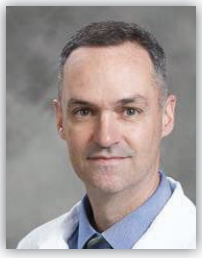
# Missouri Medicine in the News

**Did you make the news? Submit your success story and photo to hwansing@msma.org.**

*Missouri Medicine* would like to publicly thank the following non-Editorial Board experts who have done peer-review of submitted manuscripts in 2019: Angel Baldan, PhD, Doug Bogart, MD, Stephen Braddock, MD, J. Patrick Brooks, MD, Sophia M. Chung, MD, Joel Eissenberg, PhD, Muhammad Ishaq Farhan, MD, Sean Gratton, MD, Richard Hellman, MD, Charles M. Lederer, MD, Lenard Politte, MD, and Stephen Reintjes, Jr., MD.


In the fall 2019 issue *Proto* magazine, the official publication of the Massachusetts General Hospital, the feature cover story is "The Science of Near-Death Experiences" (Missouri University Press 2017). The in-category best-selling book is based on a series of articles appearing in *Missouri Medicine* and is edited by John C. Hagan, III, MD. The book is available from MSMA and on amazon.com

Mark Adams, MD, of Columbia, received the President's Award this year from the Missouri Sports Hall of Fame. His support as an MSMA member for the past 10 years is appreciated.



Golden Valley Memorial Healthcare recently announced the addition of Brian Bellamy, MD, (left) and Bruce Bellamy, MD, FAAFP, (right) to its team. These two members of MSMA have supported our efforts for a combined total of 35 years.

Congratulations to MSMA and AMA Past President David Barbe, MD, of Mountain Grove, on being elected to serve as President-Elect of the World Medical Association.


MSMA President-Elect George Hruza, MD, MBA, FAAD, of Chesterfield, was recently selected to present at the 2019 Sharm Derma Conference in Cairo, Egypt. He serves as President of American Academy of Dermatology.

The MO HealthNet Oversight Committee met in early November in Jefferson City to discuss program transformation and enrollment reforms. Bridgett McCandless, MD, an MSMA member since 2011, of Kansas City, was elected Committee Co-Chair. State Rep. Jon Patterson, MD, an MSMA member since 2011; and Randall Williams, MD, an MSMA member since 2017, also serve on the committee.

Toniya Singh, MD, FACC, MSMA member since 2015, has been named Chair of the Women in Cardiology Council of the American College of Cardiology (ACC). Her three-year appointment as Chair runs through 2022; she was initially appointed to the Council in 2017. Dr. Singh is a managing partner with St. Louis Heart and Vascular.

James Womack, MD, MSMA member since 2011, of Clinton, passed the American Board of Orthopaedic Surgery board certification.

Did you make the news? Submit your success story and photo to hwansing@msma.org.

**MM**

# *Your MSMA Council Welcome New Members!*

***(Joined between July 1-October 10, 2019)***

Shehryar M. Ahmed, DO-Kansas City
Niraj A. Arora, MD-Columbia
Austin Baker, DO-Columbia
Crystal D. Brown-Vredenburg, MD-Kansas City
Matthew C. Bunte, MD-Lee's Summit
William B. Burkhar, MD-Kansas City
Brianna Castillo, MD-Columbia
Jonathan D. Chilton, MD-Kansas City
Prema F. D'Souza, MD-Independence
Joseph C. Darrow, MD-Kirksville
Ila Durkin, MD-Columbia
Clint R. Gates, MD-Roeland Park
Daniel L. Gibson, DO-Jefferson City
Frances A. Hardaway, MD-Kansas City
George J. Harocopos, MD-St. Louis
Kimberly C. Hartman, MD-Kansas City
Lynn M. Hassman, MD-St. Louis
Lesley A. Hawley, MD-Springfield
Rakesh Hegde, MD-Springfield
Michael G. Hunt, DO-Chesterfield
Sonia F. Hussain, MD-Kansas City
Mary Anne Jackson, MD-Kansas City
Eboni C. January, MD-St. Louis
Syed M. Karim, MD-Independence
Taylor R. Lacy, MD-Kansas City
Stacey L. Leber, DO-Kansas City
Andrew R. Lee, MD-St. Louis
Robi N. Maamari, MD-St. Louis
Stephen T. Malutich, DO-Clinton
Brigid K. Marshall, MD-St. Louis
Kathleen M. Nemer, MD-Chesterfield
Edouard Oudin, MD-Columbia
Christopher W. Palmer, DO-St. Louis
Matthew Patil, MD-Columbia
Hariharan Regunath, MD-Columbia
Jennae S. Reken, DO-Columbia
Margaret M. Reynolds, MD-St. Louis
Aruna Rokkam, MD-Independence
Shawn Sahota, MD-Columbia
Carlos A. Salgueiro, MD-Kennett
Daniel E. Schneider, MD-Hannibal
Joseph B. Schneider, DO-Kansas City
Amy Schutte, MD-Webster Groves
Luke Small, MD-Cape Girardeau
Jarom H. Spence, DO-Kansas City
Lisa V. Suffian, MD-St. Louis
Harris C. Sultan, MD-St. Louis
Ahmed I. Swi, MD-Columbia
Samuel M. Taylon, MD-Kansas City
Marshall L. Taylor, DO-Kansas City
Sydnei E. Tolefree, MD-Columbia
Lawrence Tychsen, MD-St. Louis
Nicholas Uffelmann, MD-Webster Groves
Laurel A. Vaughan, MD-Columbia
Melanie J. Wahl, MD-St. Louis
Bryan D. Warner, MD-St. Louis
Cristyn L. Watkins, MD-Kansas City
Amy Zavell, MD-Columbia

# 162nd Missouri State Medical Association Annual Convention

**April 3-5, 2020 | Renaissance St. Louis Airport Hotel**

**www.msma.org/annual-convention**

# PRELIMINARY PROGRAM

## Pre-Convention Meetings

### Thursday, April 2

| | |
|---|---|
| 2:30 pm | MSMA Insurance Agency Board Meeting |
| 3:30 pm | MSMA Executive Committee |
| 3:30-6:00 pm | Convention Registration |
| 3:30-6:00 pm | Exhibitor Setup & Registration |
| **5:00 pm** | **MSMA Council Meeting** |
| **6:30 pm** | **MSMA Council Reception & Dinner** |
| 7:00 pm | Alliance Cabi Fashion Fundraiser |

## Convention Meetings

### Friday, April 3

| | |
|---|---|
| 6:30 am-4:00 pm | Convention Registration |
| 6:45 am | Moneta Group Investment Advisors Breakfast |
| **7:00 am** | **Exhibit Hall Opens/Breakfast for all Attendees** |
| **8:00 am** | **Opening Session** |
| | **MSMA House of Delegates** |
| 9:00 am | Alliance Board Meeting |
| 9:30 am | Alliance General Assembly - Session I |
| **10:00 am** | **Reference Committee A** |
| **10:30 am** | **Reference Committee B** |
| 11:00 am | Missouri Physicians Health Luncheon & Meeting |
| Noon | "Spirit of the Alliance" Awards Luncheon |
| Noon | SLMMS Caucus & Luncheon |
| Noon | KCMS Caucus & Luncheon |
| **1:30 pm** | **MSMA General Session** |
| 2:30 pm | Alliance Past President's Reception |
| **3:30 pm** | **MSMA General Session** |
| 5:00 pm | Organized Medical Staff Section Business Meeting |
| 5:00 pm | Medical Student Section Business Meeting |
| 5:30 pm | Medical School Alumni Receptions |
| 7:00 pm | Alliance Foundation Fundraiser/Dinner |
| 7:00 pm | Resident and Medical Student Mixer |

### Saturday, April 4

| | |
|---|---|
| 6:30 am-4:00 pm | Convention Registration |
| **7:00 am** | **Breakfast for all Attendees** |
| 7:00 am | International Medical Graduate Section Meeting |
| **8:00 am** | **MSMA General Session** |
| 8:30 am | Alliance General Assembly - Session II |
| **10:00 am** | **MSMA General Session** |
| 10:00 am | MMPAC Meeting |
| 10:15 am | Resident and Fellow Section Business Meeting |
| Noon | Alliance Installation Luncheon |
| 1:00 pm | AMA Issues |
| **1:30 pm** | **MSMA General Session** |
| 2:00 pm | Alliance Board Meeting |
| 2:30 pm | Missouri State Medical Foundation Meeting |
| 3:00 pm | Component/Specialty Society Leaders Meeting |
| **3:30 pm** | **General Session** |
| 5:15 pm | Reception: 50-Year Pin Recipients & MSMA Past Presidents |
| **6:30 pm** | **MSMA Presidential Inauguration** |
| **7:30 pm** | **MSMA Presidential Reception** |
| | *Entertainment, Hors d'oeuvres & Cash Bar* |

### Sunday, April 5

| | |
|---|---|
| 7:00 am | District Breakfasts & Caucuses |
| **8:15 am** | **Second MSMA House of Delegates** |
| Immediately Following Closure of the HOD | MSMA Council Meeting |

## REGISTER/RESERVATIONS

**www.msma.org/annual-convention**

Call the Renaissance St. Louis Airport Hotel at 1-800-468-3571 and mention "MSM." Group rates available until March 11, 2020. Rates start at $100 per night plus charges and taxes.

Program subject to Change. Refer to Convention Official Program for times and meeting locations. For more information, contact MSMA's Benita Stennis, at 800-869-6762 or bstennis@msma.org.

# Obesity Management, Stop the Bleed, and Medicine in the Mark Twain Era Highlights Alliance Fall Conference

*by Gillian Waltman*

Thanks to all who contributed to making the Alliance Fall Conference in Hannibal October 29-30 such a fun-filled and informative two days – especially coordinator Sandra Murdock who helped organize the events, decorated the tables with Halloween fare, and kept track of reservations. We had a good attendance. Sandra greeted everyone at the registration table on arrival and handed out festive tote bags. Everyone commented on the excellent facilities, comfortable rooms, and welcoming staff at the Holiday Inn Express opposite the Hannibal Medical Center. An excellent lunch was catered by Fiddlestiks, a local restaurant whose owner gets up early to bake her own bread and cookies, and did not disappoint!

Our Tuesday afternoon program included speakers from the Hannibal Clinic who were recommended by Sandra Ahlum, MD. Our first speaker was Eric Meidl, MD, an internist specializing in obesity mangement working closely with the bariatric surgical team. He spoke on the current management of obesity and discussed the pros and cons of various weight loss therapies and current trends, including intermittent fasting. Some understood this to mean the popular 16:8 diet in which one eats only during an 8-hour period and fasts the remaining 16 hours. (Jennifer Anniston and Hugh Jackman have done this.)

Dr. Meidl says there are many ways to accomplish this. For his obese patients he plans a custom diet to fit their needs, recommending eating only 500 calories on certain days with a larger planned caloric intake on the other days. His usual recommendation is to follow the 500-calorie intake on Mon-Wed-Fri. This is an effective weight loss method. (Jimmy Kimmel follows a similar 5:2 pattern of 5 days fasting, 2 days eating normally.) Dr. Meidl notes that after some time adhering to the diet, less food is desired on the in-between days. He mentioned that steady weight loss and good maintenance is healthy; yo-yo dieting is not. He discussed the current bariatric surgical advances and newer medical approaches to obesity. His talk stimulated much discussion and he fielded questions on childhood obesity, set points, getting past a weight loss plateau, and changes in metabolism with aging.

Patricia Hirner, MD, is a general surgeon and presented the American College of Surgeons new initiative called Stop the Bleed. This was a hands-on course aimed at the general public on how to control hemorrhage at a trauma site, such as a road traffic accident or a shooting. Sadly, the reason this ACS program was developed was because of reports after the school shooting at Sandy Hook that one-third of the children who died could have survived if those around them had known how to control bleeding. Michael Bukstein, MD, a vascular surgeon at the Hannibal Clinic, assisted in the demonstration which included the correct methods of applying compression to a bleeding wound, packing the wound with clean cloth or hemostatic gauze, and the use of tourniquets. In the old Girl Scout days, we were taught to use anything we could devise for a tourniquet and to release the pressure after 20 minutes to allow some blood flow. That is no longer recommended; a professional tourniquet should be used that remains on until the patient is transported to medical care.

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The lightweight velcro tourniquet Dr. Hirner showed can be applied like a blood pressure cuff; a small rod is turned to tighten the cuff until the bleeding stops. It is then snapped in place and a tag is labelled with the time the bleeding stopped, remaining on the injured patient while they are transported. Dr. Bukstein says he can restore circulation to a limb up to six hours after a tourniquet is applied. Even if a limb cannot be saved, wearing the tourniquet gives the patient a much better survival rate. Dr. Hirner recommended that everyone carry a trauma kit with these contents in the glove compartment of their vehicles.

Missouri State Medical Association Alliance President Gill Waltman (left) welcomes from left, Drs. Michael Bukstein, Patricia Hirner, and Erik Meidl to the MSMA Alliance's Fall Conference in Hannibal on Oct. 30. Drs. Bukstein and Hirner presented on the ASC program Stop the Bleed, while Dr. Meidl spoke on Obesity Management. The physician members of MSMA are all from the Hannibal Clinic.

Our Tuesday evening event was held at the Hannibal Country Club. Sherry and Michael Bukstein are members and had secured the venue for us. Our after-dinner speaker was Henry H. Sweets, III, the Curator and Executive Director of the Mark Twain Boyhood Home and Museum. Alliance member Mary Catherine Heimburger invited Henry, a childhood school friend, on our behalf. Henry grew up in Hannibal and is considered an international expert on Mark Twain. He spoke on Medicine and Pharmacy in the time of Mark Twain. He described Samuel Clemens' early life and how the family came to live in Hannibal.

Missouri State Medical Association Alliance "rises to the AMA Alliance Peanut Butter Challenge" by collecting and donating jars of peanut butter to a Hannibal Food Bank.

It is hard to imagine managing severe illness and injury without anesthesia, antibiotics and analgesics, not to mention antisepsis. Remedies from plant roots such as calomel and jallup (jalop) were used as purgatives and fungicides which would have been quite ineffective against the cholera epidemic of 1849 or various later challenges with yellow fever. Clemens contracted measles when he was ten and almost died. Dr. Sweets led us through the life of Clemens, his presentation being peppered with Twain quotes and a few Norman Rockwell depictions of Twain's stories. The fifteen original Rockwells, (except one!) were on display in the Mark Twain Museum at the time of our visit. Dr. Sweets was an engaging speaker and provided entertaining and interesting information.

Several of us met downtown on the riverfront after the board meeting on Wednesday morning. After lunch at the Mark Twain Brewing Company, where we had a private upstairs room and a view of the river, we went on a tour of the Mark Twain Boyhood Home and Museum. **MM**

## Missouri State Medical Association Alliance

# Holiday Sharing Card

**From the following who most generously gave to the Missouri State Medical Foundation and to the American Medical Association Foundation.**

## We bring you tidings of good cheer, & wish you a happy, healthy & peaceful New Year.

Dr. Sandra Ahlum & Dr. Lent Johnson
Dr. Erol & Sally Amon
Dr. David & Debbie Barbe
Jim Braibish & Diane Hammill, OD
Dr. Michael & Sherry Bukstein
Dr. Edmond & Rima Cabbabe
Drs. Samer Cabbabe & Amy Cabbabe
Dr. David & Eileen Chalk
Dr. Jim & Marsha Conant
Dr. Joe & Donna Corrado
Mrs. Diana Corzine & Jason Corzine
—in honor of John Corzine, DO
Dr. Michael DePriest & Barbara A. Braznell
Dr. Laura & Kirk Doan
Dr. Jon & Patricia Dehner
Dr. Thomas & Sue Ann Greco
Dr. John & Rebecca Hagan
Drs. John Holds & Sophia Chung
Mrs. Joan H'Doubler
Mary Catherine Heimburger
Dr. Alex & Barbara Hover
George Hruza, MD & Carrie Hruza, OD
Dr. Ravi & Kay Johar
Dr. Jerry & Michele Kennett
Dr. Nathaniel & Sandra Murdock
David & Jill Nowak
Dr. Timothy & Kelly O'Leary
Mrs. Jean Raybuck
Drs. Carlin Ridpath & Louis DelCampo
Dr. JoEllyn Ryall
Dr. George & Sana Saleh
Dr. Ross & Mary Shuman
Dr. Christopher & Kate Swingle
Dr. Jeff & Gail Thomasson
Dr Tom & Anne Turnbaugh
Dr. Stephen & Gill Waltman
Mrs. Liz Webb
Dr. Tom & Kathy Weigand
Dr. Jim & Jana Wolfe
Dr. Michael & Allene Wright
—in memory of Carol Jean Defeo
Mrs. Angela Zylka

# Pickleball: Injury Considerations in an Increasingly Popular Sport

*by Nicholas Greiner, DO*

## Are the benefits worth the risks? With a few precautions, yes for most people.

Pickleball is a recreational sport that is gaining in popularity and has become one of the fastest growing sports in America. The sport is easy to learn, promotes competitiveness and socialization, and is a great form of low impact exercise.

The game was developed in 1965 by a former Washington state congressman, Joel Pritchard. He and a friend were looking to play badminton, but unable to find a full set of rackets they improvised, playing with wooden ping-pong paddles and a perforated plastic ball. With this collection of equipment, they played on an asphalt surface using a badminton net adjusted to a height similar to that of tennis. The friends eventually developed a permanent set of rules. Their intention was to develop a sport the entire family could enjoy together. Within two years, the first permanent court was constructed next door to Joel Pritchard's home. Within a few more years, a corporation was developed to protect the sport. Since its inception, the game has continued to grow, and is now played in all 50 states.

There are differing reports on how the sport developed its interesting name. According to Joel Pritchard's wife, she started calling the game Pickleball because the combination of elements of multiple sports reminded her of the pickle boat in crew, where oarsmen were chosen from the leftovers from other boats. However, according to other accounts, the game was named after the Pritchards' dog, Pickles. In the early development of the game, there no official name assigned to it. As the game progressed, an official name was needed, and "Pickleball" was it.

Pickleball is currently the fasting growing sport in the US.[1] The Sports & Fitness Industry Association (SFIA) estimated that in 2017 there were over 2.8 million Pickleball players in the U.S., which was an increase of 12.3% from the previous year.[1] Further details from the 2016 SFIA report included that over 1.5 million people were 'casual' participants (play one to seven times per year), and that 930,000 were 'core' participants (play eight or more times per year). Further breakdown of participation rates by age showed that 'core' participants tend to be older, with 75% of core participants being age 55 or older, and 42% of all players over 65 considered to be core participants. Along with fitness benefits of the sport, many older adults enjoy playing Pickleball because it promotes competitiveness and socialization.[2,3]

### Rules

Pickleball can be played indoors or out, on a court that is 20 ft. by 44 ft. This is comparatively much smaller than a tennis court (36 ft. by 78 ft). Like tennis, Pickleball can be played as doubles or singles, but the court dimensions do not change for the doubles game. The net is slightly lower for Pickleball at 34 inches at the center, compared to 36 inches for tennis. There is a seven foot no-volley zone that extends from each side of the net (Figure 1).

The premise of the game is similar to other racket sports. To score points, a player hits a hard plastic ball with holes (similar in size to a Wiffle ball) over the net with a wooden or composite racket. The racket is larger than a ping-pong paddle, but smaller than a tennis racket. Serving is performed underhand, with the server making contact with the ball below the waist. The receiving opponent returns the ball within bounds of the court, but outside the no volley zone. Once the ball bounces once on each side, a volley ensues. The serving team continues to serve until a fault occurs. A fault can occur if the ball touches any part of the no-volley zone on the serve, is hit out of bounds, does not clear the net, is volleyed from the no volley zone,

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or is volleyed before a bounce has occurred on each side. Only the serving team can score. If the serving team commits a fault, the serve passes to the other team. Games typically are played to 11, 15, or 21 points, with the winning side required to win by two points.


Figure 1. USAPA Regulation Pickleball Court

## Associated Injuries

A recent literature search did not reveal any published research describing specific injuries related to Pickleball.[4] However, there is published research on injuries associated with other racket sports. In tennis, a similar style racket sport played on a similar surface, the most common injuries are sprains/strains of the lower extremity, followed by sprains/strains of the upper extremity and injuries of the trunk and low back.[5,6,7] Given the underhand nature of the game play of Pickleball, one would expect a lower occurrence of shoulder injuries than in tennis where overhand serving is a major component of the sport. However, there is still a risk for a variety of other upper extremity injuries in Pickleball.

## Acute Injuries

Acute traumatic injuries in Pickleball can result from falls, secondary to a sudden turning or pivoting movement. Sprains of the ankle joint, particularly with inversion, are very common in tennis and the mechanism for this injury would be similar for Pickleball. Depending on the severity of the sprain, this injury could result in significantly impaired movement or inability to bear weight. If weight bearing is painful, initial treatment may initially include crutches (if needed), or immobilization with an ankle brace. Further treatment consisting of relative rest, icing, compression, and elevation (RICE) are generally useful in the treatment of sprains of the ankle and other joints. Depending on severity, ankle sprains can take several weeks to resolve, but patients can generally resume their previous level of play if proper steps are taken during the healing process. Return to sport participation for this and other injuries is often expedited by physical therapy.

Other injuries that can arise near the ankle can involve the Achilles tendon. These can include an Achilles strain, which can present as pain anywhere along the tendon, from the musculotendinous component at the lower calf muscle, to the body of the tendon, to its insertion at the calcaneus. Treatment of Achilles tendon strains typically consists of relative rest, focused stretching of the tendon, and eccentric loading exercises. This injury can take weeks to fully heal. A much less common but more severe injury, Achilles tendon rupture, can occur with forceful movement of the ankle, usually an abrupt plantarflexion. This injury usually results in severe pain in the posterior ankle and an inability to bear weight or actively plantarflex the foot. This type of injury will often require surgical repair, and should be evaluated promptly for optimal long term outcome.

Knee injuries are also common in racket sports such as tennis,[5,7,8] and likely to affect Pickleball players as well. These can range from acute sprains of the knee, to meniscal and ligamentous injuries. A sprain of the knee can affect the collateral ligaments, caused by rapid starting/stopping and sudden turning or pivoting movements. A sprain will often result in pain with weight bearing, usually worse with lateral movement. Acute injuries of the meniscus can include tears, which can present with the same mechanism as a ligament sprain, but often will result in the inability to bear weight, decreased range of motion, and significant swelling. Treatment of these injuries can range from initial non-weight bearing, to bracing, to physical therapy, or even potential surgical repair. Any knee injury that results in pain with weight bearing, decreased range of motion, or significant swelling should prompt immediate evaluation by a physician.

Muscle groups in the lower extremity that can be

acutely strained include the hamstring muscles, quadriceps, hip flexors and adductors, and calf. Many strains can involve partial tearing of the muscle body or tendon. These injuries can present as pain in the muscle with stretching or muscle contraction. Mild sprains usually respond to RICE treatment, and participants can usually return to their activity in a matter of a few weeks. More severe muscle strains or tears may have more severe pain, associated swelling or bruising of the muscle, and tend to take longer to recover. As stated above, many of these injuries will respond well to physical therapy, and this can often help to assist players to return to their previous level of competing, and can often address other potential biomechanical inefficiencies that can be future injury risks.

For the upper extremity, the wrist is a common site of tennis injury, and Pickleball players are at risk as well (Figure 2). Falls onto an outstretched hand are a common mechanism for wrist sprains, and can also result in a fracture. The elbow and shoulder can also be injured by falls. Minor bruising to the upper extremity may be initially treated with RICE, but an injury to the upper extremity that causes significant swelling, bruising, or limited range of motion should prompt a player to be evaluated.

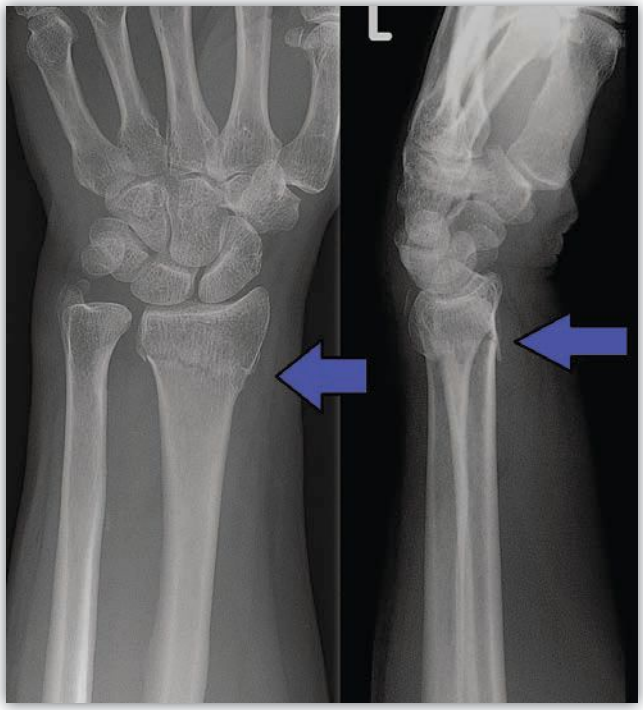

Figure 2. X-ray of a Colles' fracture of the left wrist accompanied by an ulnar styloid fracture. This injury is commonly associated with falls onto an outstretched hand.
*Source: wikipedia*

## Chronic Injuries

Chronic injuries that can affect Pickleball players will typically result from overuse or repetitive pounding on the hard playing surface. In the foot, these can include plantar fasciitis and heel contusions. Plantar fasciitis typically results from irritation of the fascia that originates at the calcaneus and extends along the medial arch of the foot. This is typically treated with activity modification, stretching, intrinsic foot exercises, and potentially shoe orthotics or heel cups. Heel contusions, or bruises of the calcaneus, are treated with relative rest and localized padding or footwear modification. Blistering of the foot can also be an issue, particularly with prolonged use of improper footwear. To limit the potential for foot injuries, a player should make sure they have proper fitting shoes.

As previously mentioned, strains of the gastrocnemius, hamstring, quadriceps, or groin can be acute, but also can occur over time, presenting as gradually worsening muscle pain with prolonged use of the affected area. If a player is having persistent soreness in these muscle groups, focus should be placed on stretching the affected area and avoidance of offending activity until symptoms improve.

Lumbar muscle strains are a common injury,[9] often associated with forward bending and repetitive trunk rotation while striking the ball. Initial management of lumbar strains is similar to strains of other muscles with RICE treatment. Preventive conditioning strategies to limit low back muscle injuries include core stability lower extremity flexibility training.[9] This is another injury for which physical therapy can help an athlete return to their level of play. Low back injuries that do not respond to the above conservative measures may warrant MRI or other imaging to assess for more significant injury such as disk or vertebral injury.

In the upper extremity, flexor and extensor tendon strain at the wrist can develop, as well as epicondylitis injuries at the elbow. These are overuse injuries associated with repeated ball striking, and can be limited by proper ball striking form. Once present, these injuries often respond to rest, focused stretching and gentle resistance exercise targeting the injured area. Bracing of the wrist or elbow can also potentially provide increased comfort and stability while healing.

Chronic shoulder injuries would be expected to occur less frequently in Pickleball given the predominantly underhand play, but strains of the rotator cuff could occur with overhand volleys or repetitive stretching to reach for the ball. As with other muscle strains, these injuries will often improve with relative rest. Stabilization and range of motion exercises for the shoulder can be used to facilitate

Figure 3. Pickleball tournaments are popular as vacation destinations.

recovery and a return to normal function. If a patient's progress plateaus with a shoulder or the other mentioned areas, treatment with a skilled physical therapist can help restore proper strength, balance and motion to allow a player to resume pain-free activity.

## Equipment

There is not a lot of individual equipment required for Pickleball, other than a racket. However, proper footwear can help prevent acute and chronic injury. Making sure that shoes fit properly and limit sliding of the foot can prevent excess friction on the foot. Given the need for lateral stability due to rapid side to side movements, cross-training or court shoes would be preferred to running shoes. For people with chronic ankle pain or instability issues, an ankle brace with laces and/or straps may help provide lateral stability. Likewise, for participants with chronic knee pain or stability issues, a lightweight compressive knee brace may provide increased comfort and stability.

## Injury Prevention

For more general injury prevention, regular cardiovascular exercise outside of Pickleball can help limit fatigue associated with play. The United States Office of Disease Prevention and Health Promotion recommends 150 minutes of moderate intensity aerobic physical activity per week.[10] If one is not playing Pickleball for 150 minutes every week, then cardiovascular exercise including running, jogging, or lower impact activities such as biking, elliptical machine, pool walking or swimming can help promote general fitness.

Pickleball is an easy to learn, low impact exercise that can be enjoyed by most people. However, if a person has significant cardiovascular or pulmonary conditions that limit their ability to exert themselves, participating in Pickleball or other exercise activities should be discussed with their physician. Also, if a person has a functionally limiting musculoskeletal problem such as severe osteoarthritis, one should be cautious when beginning Pickleball, given the hard surface and recurrent impact with quick steps and rapid starting and stopping.

## Conclusion

Pickleball is a very popular and rapidly growing sport. Given its ease of play and low impact nature, it can be an enjoyable way for people of all ages to stay active and fit and help to promote a healthy lifestyle. As with all sports, there is a risk for a variety of injuries. However, taking a few steps in preparation coupled with proper knowledge of one's own health, Pickleball can be an enriching activity enjoyed by players of all ages (Figure 3).

For more information about Pickleball, visit the USAPA website at usapa.org.

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# Vaping Associated Lung Injury (EVALI): An Explosive United States Epidemic

*by Gary A. Salzman, MD, Mohammed Alqawasma, MD & Hussein Asad, MD*


UMKC School of Medicine

**Physicians should be vigilant in identifying and reporting cases of EVALI and strongly discourage the use of electronic cigarettes and vaping products.**

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## Abstract

**As of November 5, 2019, there have been 2051 cases of e-cigarette, or vaping, product use associated lung injury (EVALI), with 39 deaths reported in the United States, over four months. The rapidly increasing popular habits of vaping and e-cigarette use has suddenly turned deadly in the United States. This epidemic of vaping-associated illness appears to be limited to the United States with few reported cases and no deaths from the rest of the world.**

## Introduction

Electronic cigarettes are battery-powered devices that produce an inhaled aerosol by heating a liquid that contains nicotine, flavorings, and other chemicals[1] (Figure 1). Commercially available devices are available to purchase legally for adults that contain various amounts of nicotine and flavors. The term vaping is used because of the perception that the exhaled smoke is water vapor. It actually consists of fine particles of chemicals.[1] The vaping device consists of a mouthpiece, a battery, a cartridge for containing the e-liquid or e-juice, and a heating component for the device. When the device is used, the battery heats up the heating component, which turns the contents of the e-liquid into an aerosol that is inhaled into the lungs and then exhaled.[1] Vaping devices include not simply e-cigarettes, but also vape pens and personal vaporizers (also known as 'MODS').[1] The e-liquid in vaporizer products usually contains a propylene glycol or vegetable glycerin-based liquid with nicotine, flavoring, and other chemicals and metals but not tobacco.[1]

The electronic cigarette company, JUUL, has developed a product that resembles a USB flash drive to deliver high doses of nicotine.[2] One pod contains the same amount of nicotine as 20 cigarettes. JUUL entered the U.S. market in 2015 and their design has become popular with teenagers as they are easy to hide from parents and teachers.[2] The JUUL product has become the most popular vaping device on the market, accounting for 72% of vaping products in the U.S[2] (Figure 1).

Electronic cigarettes were approved for use in Europe in 2006 and in the United States in 2007.[3] The use of electronic cigarettes and vaping has exploded in the United States over the last 12 years. In 2018, more than 3.6 million U.S. middle and high school students had used electronic cigarettes in the previous 30 days.[1] In 2015 the CDC

reported more than nine million Americans vaped on a regular basis. [1]

Vaping stores provide customized e-juices that can be used in devices to deliver various combinations of flavors and nicotine concentrations. Tetrahydrocannabinol (THC), the psycho-active component of cannabis, is added to electronic cigarettes alone and in combination with nicotine. Many of the products containing THC are purchased from illicit dealers and often contain potentially toxic substances such as Vitamin E and Cannabidiol (CBD) oils.[3, 4] In states with legalized marijuana for medical or recreational use, commercially manufactured products containing THC are sold legally. Highly concentrated THC or nicotine concentrates prepared in a wax like substance and smoked in a pipe is a process called "dabbing". Vaporizing extracts of a concentrate of butane hash oil or nicotine that has been placed on a hot surface is called "dripping".[4, 5]

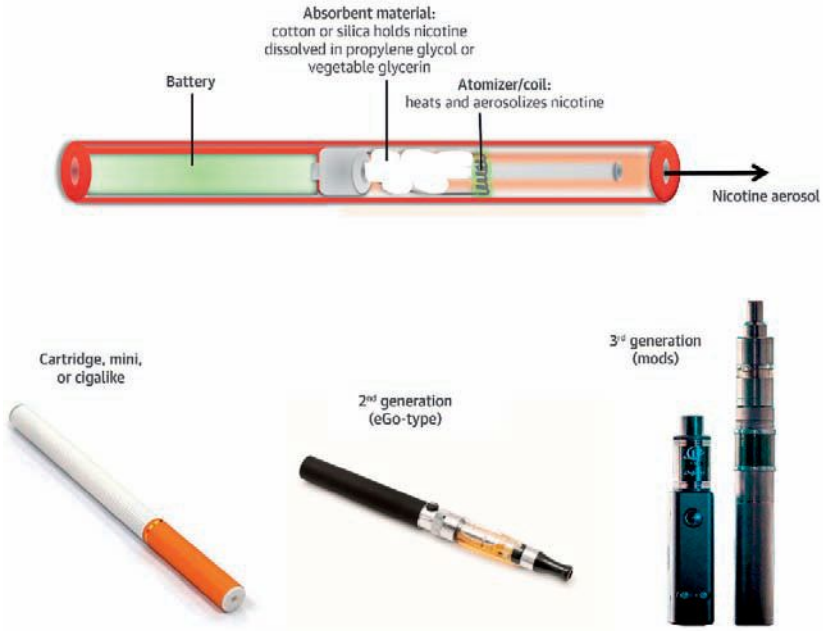


Figure 1. Schematic Diagram of the Elements of an Electronic Cigarette and Pictures of Three Generations of Electronic Cigarette Devices
*Source: Journal of the American College of Cardiology 2015*

## Clinical Vignette

A 27-year-old Caucasian female with no prior history of asthma or other lung diseases was admitted to the intensive care unit with a five-week history of dyspnea associated with dry cough and bilateral sharp chest pain increased with deep inspiration. She was evaluated in the emergency department (ED) two weeks prior to admission. Her oxygen saturation at the first ED visit was initially 84% on room air with wheezes auscultated on lung exam. After nebulized treatments with albuterol and ipratropium, her oxygen saturation improved to 97% on room air. A CT angiogram of the chest identified no pulmonary emboli. Bilateral upper lobe ground glass infiltrates were noted on the CT chest. White blood cell count was 24,400 with 47% eosinophils. She was treated as an outpatient with an albuterol inhaler and a five-day course of azithromycin. Her cough and dyspnea initially improved and then increased two days prior to admission.

She reported vaping for at least three years. Initially she vaped both nicotine and THC products, but over the three months prior to admission she was vaping exclusively JUUL pods with 5% nicotine (about 2 pods/day) blueberry and mint flavors. She also occasionally smoked tobacco cigarettes and marijuana joints. After her first emergency department visit, two weeks prior to admission, she stopped vaping and noted less cough and dyspnea. She then started vaping JUUL pods a few hits per day up to the day of admission when she presented with increased cough, dyspnea, and pleuritic chest pain.

In the emergency department on the day of admission, she was found to be hypoxic requiring six liters per minute supplemental oxygen to maintain oxygen saturations of 93%. She was admitted to the ICU for management. Arterial blood gas on FiO2 of 40% revealed pH of 7.287, PaCO2 52 mmHg, PaO2 of 64 mmHg, HCO3 24 mEq/L, O2 saturation 93%. Alveolar arterial gradient of 161 mmHg. Her initial vital signs were temperature 98.3, blood pressure: 109/74 mmHg, heart rate 102, oxygen saturation of 93% on 6 liters of supplemental O2, and respiratory rate of 20. Physical exam was only remarkable for diffuse bilateral crackles with end expiratory wheezes on lung exam. The chest x-ray revealed subtle patchy heterogeneous opacities bilaterally (Figure 2). The CT of the chest revealed increased ground glass opacities of bilateral lungs, predominantly in the upper lobes (Figure 3).

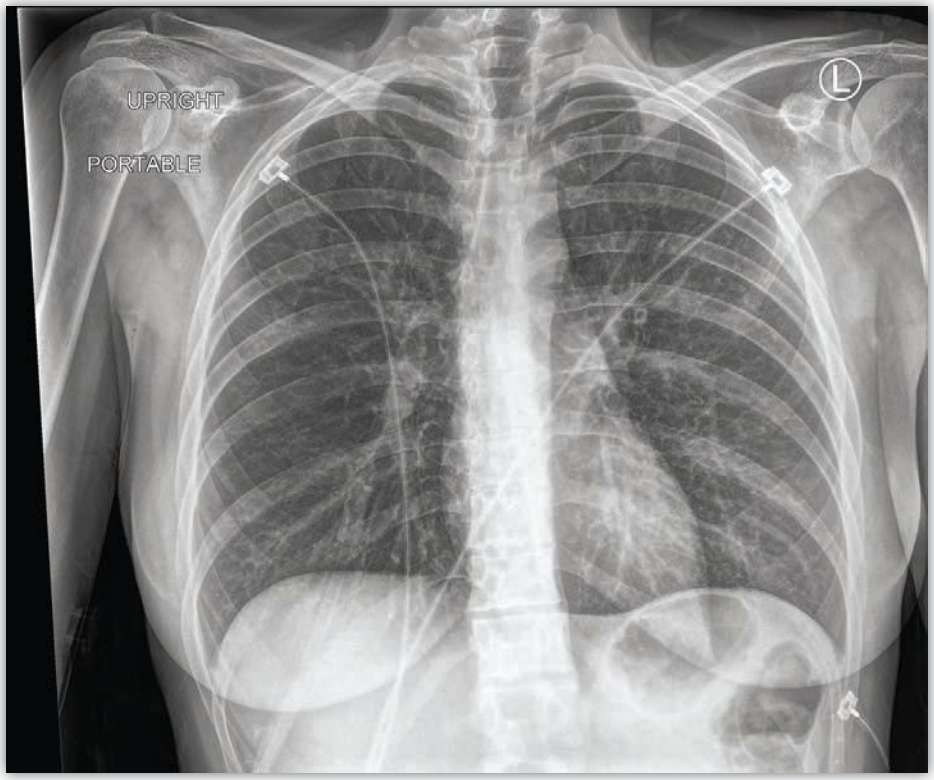


Figure 2. (second ED CXR) Chest x-ray at time of admission showing subtle bilateral patchy infiltrates.

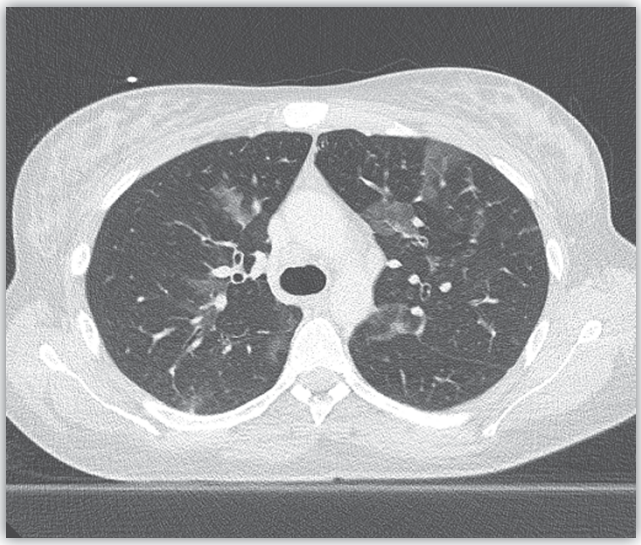

Figure 3. (second ED CT scan) Chest CT at time of admission showing bilateral upper lobe ground glass opacities.

White blood cell count was 23,000 with 18% eosinophils. Urine streptococcus and legionella antigens negative, serum mycoplasma antibody was negative, T spot for tuberculosis and HIV were both negative.

She was treated with oral prednisone 50 mg daily for a total of 5 days. Given the concern for infection, the patient was also started on oral doxycycline 100 mg twice a day for a period of five days. During hospitalization, she had significant improvement of her symptoms. She was treated for one day in the intensive care unit and an additional three more days in the hospital. Her oxygen requirements continued to decrease and the patient was discharged to home off supplemental oxygen after a total of four days of hospitalization. She had no oxygen desaturation on room air with a six-minute walk the day of discharge. The patient was scheduled for follow-up in the pulmonary clinic two weeks after discharge for repeat imaging, complete blood count, and pulmonary function testing. She did not keep her appointment.

With the presence of significant peripheral eosinophilia, patchy ground glass infiltrates, hypoxemia, and a history of vaping, this patient most likely had acute eosinophilic pneumonia associated with electronic cigarettes. Acute eosinophilic pneumonia has been reported in individuals using nicotine containing electronic cigarettes.[6,7,8] In idiopathic acute eosinophilic pneumonia the duration of corticosteroid treatments is usually at least two weeks.[9] Once the patient we described had completely stopped vaping during her hospitalization her symptoms improved rapidly and she only required five days of oral corticosteroids.

## E-cigarette, or Vaping, Product Use Associated Lung Injury: EVALI

The number of reported cases of EVALI in the United States has exploded over a four month time period. As of November 5, 2019, 2051 cases of EVALI have been reported with 39 deaths.[10] Seventy percent of cases were in males and 79% in patients less than 35-years old.[10] Fourteen percent of cases were less than 18-years old.[10] Eighty-six percent of patients reported using THC-containing products and only 11% reported using nicotine products exclusively.[10] Thirty-four percent of patients reported exclusive use of THC-containing products.[10] Patients may be reluctant to report use of THC or purchasing products from illicit dealers.

The vast majority of patients (95%) present with respiratory symptoms of cough, chest pain, and shortness of breath.[11] Many patients will reduce, but not eliminate, vaping after the onset of respiratory symptoms. Constitutional symptoms of fever, chills, and weight loss occur in 85% of patients.[11] Gastrointestinal symptoms of abdominal pain, nausea, vomiting, and diarrhea occur in 77% of patients and can be the initial symptoms preceding respiratory symptoms.[11] Symptoms usually progress in severity over one to two weeks.[11] Tachycardia and tachypnea associated with pulse oximetry less than 95% are common.[11] Auscultation on lung exam is often normal. Non-specific findings of leukocytosis, elevated erythrocyte sedimentation rate and elevated liver transaminases have been reported.[11]The chest radiograph is abnormal in the majority of cases revealing patchy infiltrates.[12] CT of the chest commonly demonstrates basilar-predominant consolidation and ground-glass opacities, often with areas of lobular or sub pleural sparing.[12]

The clinical course is usually associated with progressive hypoxemia requiring high flow oxygen and in 22% of cases mechanical ventilation for Acute Respiratory Distress Syndrome (ARDS).[11] Most patients have been treated with antibiotics to treat severe community acquired pneumonia, and varying doses and duration of corticosteroids.[11] Microbiology specimens for bacteria, viral, and fungal organisms are usually negative. When Broncho-alveolar-lavage (BAL) specimens are obtained, lipid-laden macrophages have been identified.[11]

Eosinophils have been identified in broncho-alveolar lavage or peripheral blood specimens in a few cases, such as the one reported in this article, suggesting acute eosinophilic pneumonia.[6,7,8] Surgical lung biopsies reveal mild and nonspecific inflammation, acute diffuse alveolar damage, organizing pneumonia, acute fibrinous pneumonitis, chemical pneumonitis, foamy macrophages, lipoid pneumonia, and interstitial and peribronchiolar granulomatous pneumonitis.[13] Lipoid pneumonia has been reported from the use of THC-containing vaping cartridges and pens.[14] Hypersensitivity pneumonia with ARDS was reported in an 18-year-old nicotine-only electronic cigarette user.[15]

## EVALI Diagnosis Is by Exclusion

Specific diagnostic criteria for EVALI have not been established.[11] It is a diagnosis of exclusion in patients presenting with a recent history of electronic cigarette use or vaping nicotine, and/or THC containing products with respiratory, constitutional, and/or gastrointestinal symptoms. Oxygen saturations less than 95% are reported in 57% of cases.[11] Evaluation for infectious and inflammatory causes of the illness should be investigated based on the clinical history.

## Management of EVALI

Physicians should routinely question patients about vaping and use of electronic cigarettes. Hospital admission is recommended for patients with oxygen saturations less than 95% on room air with suspected EVALI.[11] Patients may develop severe hypoxemia and respiratory failure 24-48 hours after presenting with mild symptoms.[11] A detailed history and physical should be performed. Rapid testing for influenza should be performed during the influenza season, as this may have a similar presentation to EVALI. All patients should have a chest x-ray and patients with moderate and severe symptoms or hypoxemia should have a CT of the chest. A complete blood count with manual white blood cell differential should be performed to detect peripheral eosinophilia. Microbiology specimens from sputum and blood should be obtained.

It is important not to miss other causes of respiratory and gastrointestinal symptoms. Treatment with antibiotics directed against organisms causing severe community-acquired pneumonia should be started at the time of presentation. Oral or intravenous corticosteroids should be started in consultation with a pulmonologist recognizing that some infections may worsen with corticosteroids.[11] The dose and duration of corticosteroids

has not been established. Once the patient has clinically improved, with oxygen saturations greater than 89% on room air, they should be considered for discharge. Patients should have a follow-up visit after discharge in one to two weeks, with a chest x-ray and pulse oximetry. The long-term consequences of EVALI are unknown, so pulmonary function tests, six-minute walk pulse oximetry, and CT chest may be considered one to two months after discharge.

## Unanswered Questions About EVALI

Unanswered questions remain about the recent explosion of EVALI cases. Why are we seeing these cases now and not over the preceding 12 years? The majority of cases are related to use of THC-containing products.[10] It is possible this epidemic of acute lung injury cases is related to a recent widespread adulteration of THC-containing illicit vaping products. A common finding in published case series is the prevalence of use of a cannabis product known as "Dank Vape."[4,5] Dank Vapes are counterfeit brands available online and used by distributors to market THC-containing cartridges.[4,5] How do we explain EVALI cases in patients, like the one we reported, who claim to only use commercially available nicotine electronic cigarettes? Was our patient being truthful? Has there been a change in the manufacturing of these products? Are the lung injury cases a result of the marked increased number of electronic cigarette users in the USA? Why are we not seeing more EVALI cases reported in countries other than the USA? The United Kingdom (UK) has placed restrictions on the import of selected vaping products, limits the amount of nicotine within these products, and has placed restrictions on the advertising of electronic cigarettes.[16] Electronic cigarettes are promoted as an acceptable smoking cessation tool in the UK and are not as popular with youth as they are in the USA[16] What causes the gastrointestinal symptoms common among patients presenting with EVALI? It is possible gastrointestinal symptoms are related to synthetic marijuana as the source of the THC vaping fluid.

## Conclusion

We report a case of acute eosinophilic pneumonia associated with commercially available electronic nicotine cigarettes, responding to a short course of oral corticosteroids and cessation of vaping. There are likely multiple mechanisms of lung injury in EVALI cases. Acute eosinophilic pneumonia and hypersensitivity pneumonitis appear to be more associated with nicotine-only electronic cigarettes. Acute eosinophilic pneumonitis may be underreported due to the unavailability of a manual white blood cell differential to accurately identify peripheral eosinophilia. Lipoid pneumonia, diffuse alveolar damage, acute fibrinous pneumonitis, and chemical pneumonitis appear to be more associated with THC containing products. Physicians should be vigilant in identifying and reporting cases of EVALI and strongly discourage the use of electronic cigarettes and vaping products.

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## Disclosures

None reported. **MM**

# The Brave New World of Gene Editing and Molecular Medicine

*by Joel C. Eissenberg, PhD*

**Somatic cell genome editing is certain to become standard therapy for many inherited diseases.**

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## Abstract

**Gene therapy has long been a promise of molecular biology. So far, that promise has largely been unrealized. The advent of gene editing using technology adapted from bacteria may finally usher in the era of gene therapy.**

## Introduction

Humans have been modifying the genomes of diverse organisms for centuries. The extraordinary variety of dog breeds, for example, attests to the power of selective breeding. The familiar livestock and crops that comprise much of our diet are also the result of extensive genome modification resulting from a combination of random mutations and artificial selection.

With the advent of molecular cloning, genetic modification has taken the form of inserting foreign DNA into the genomes of plants and animals. The first published description of a transgenic animal was in 1974, a mouse into which had been introduced simian virus 40 DNA.[1] The first transgenic plant was reported in 1983.[2] Today, many transgenic crops have been engineered to carry foreign genes that confer insect resistance and herbicide tolerance and genetically engineered transgenic livestock carry foreign genes that enhance milk and meat production.

The application of genome modification in humans has been much more limited. The first gene therapy was performed in 1990 for two patients suffering from severe combined immunodeficiency due to lack of the enzyme adenosine deaminase (ADA). A functional ADA gene was introduced into cultured patient T cells using a recombinant virus, then the T cells were re-infused into the patient. Both patients showed somewhat improved immune responses after this treatment, although the gene therapy alone was not curative. Later advances in stem cell gene therapy improved on these initial results.[3]

ADA deficiency was an ideal candidate for gene therapy for several reasons:[4]

- the gene is relatively small, making a recombinant version for gene therapy technically easy to create;
- ADA expression levels vary widely across healthy individuals, implying that tight regulation of the therapeutic copy was not necessary;
- correct ADA expression in just some cells is sufficient for therapeutic effect, since the enzyme catalyzes a reaction that produces a product that can complement cells that still lack the enzyme;
- the effects of the disease are completely reversible;
- delivering the therapeutic gene to T lymphocytes is straightforward compared to other tissues or organs.

Clinical gene therapy was dealt a temporary setback with the death of Jesse Gelsinger, who died at the age of 18 four days after being injected with a recombinant adenovirus as part of a clinical trial to treat ornithine transcarbamylase deficiency. His death was the result of an overwhelming immune response triggered by the virus. After extensive investigations, the NIH and FDA devised new programs for patient protection that allowed clinical applications of gene therapy to resume. Currently, more than 2,600 gene therapy clinical trials have been approved, are underway or have been completed.[5]

So modifying genomes is not new. What is new is the unprecedented degree of precision afforded by the latest gene editing technology. The goal of genome editing is not simply to supplement the genome with additional genetic material, it is to edit the existing genetic information to correct or inactivate a gene.

## How Does CRISPR/Cas9 Work?

The CRISPR/Cas9 system was first discovered in bacteria, which use it to attack infecting viruses. As the mechanism of the bacterial system has been worked out, the key elements have been identified and streamlined for use in any cell type.[6] The basic mechanism of CRISPR/Cas9 DNA editing is cartooned in Figure 1. The two key components of the editing machinery are (1) a "guide" RNA that recognizes a specific site in the genome for editing and brings the Cas9 DNA-cleaving enzyme to the site, and (2) the Cas9 enzyme that cuts both strands of DNA at the target. There are two fates for the target DNA after cleavage by Cas9. One is that the two broken ends are reunited by an error-prone cellular repair mechanism called "non-homologous end joining." This frequently results in the loss or gain of DNA nucleotide subunits at the site of cleavage, which can render the resulting DNA sequence non-functional if it encodes a protein or otherwise directs gene expression. The other outcome depends on the presence of an identical copy of the target DNA sequence carried by a separate DNA molecule. This mechanism, called "homology-directed DNA repair," can be exploited in genome editing to replace the target DNA sequence with a modified sequence that either creates or corrects a mutation.

Strategies for genome editing have existed for a couple of decades. What makes CRISPR/Cas9-based genome editing so exciting is the high specificity of targeting conferred by the pairing of the guide RNA with the target DNA. With six billion subunits, or nucleotides, of DNA in the human genome, the chance that there exists a close match to the desired editing target elsewhere in the genome is significant. Off-target edits must be avoided, as they could result in unknowable pathologies. Accordingly, much research is focused on maximizing the specificity of CRISPR/Cas9. Compared to the gene therapy for ADA deficiency, CRISPR/Cas9 editing doesn't depend on the size of the target gene or how the gene is regulated normally.

When applied to human disease, there are two forms of clinical genome editing that are feasible, somatic cell genome editing and germline genome editing. Each strategy has its challenges.

### *Somatic Cell Gene Editing*

Somatic cell genome editing involves destroying or correcting a mutant gene in order to restore healthy function to the patient. The effects of somatic cell editing are restricted to the patient and can't be transmitted to their progeny. A partial list of some inherited diseases amenable to therapeutic somatic cell gene editing is given in Table I.

In November of 2018, Editas Medicine and Allergan received FDA approval for CRISPR/Cas9 somatic cell genomic editing to treat Leber's congenital amaurosis type 10, the most common form of inherited childhood blindness. In January of 2019, the FDA announced fast-track approval for clinical trials of a CRISPR/Cas9 somatic cell genome editing strategy for sickle cell disease.

The biggest challenge for somatic cell genome editing is efficiently delivering editing CRISPR/Cas9 complexes to the appropriate target tissues in therapeutically meaningful amounts. There are a variety of potential strategies to deliver the editing molecules to the cells to be edited,[7] the mechanistic details of which are beyond the scope of this review. For hematopoietic disorders, such as beta-thalassemia, sickle cell disease and severe combined immunodeficiency, culturing patient bone marrow stem cells, editing the stem cell genome ex vivo, and re-grafting the edited cells is technically straightforward. Furthermore, only a fraction of the hematopoietic stem cells need be successfully edited for the patient to experience substantial relief from disease symptoms. For genome editing delivered to other tissues or solid organs, viral vectors encoding the CRISPR/Cas9 components may prove to be the most efficient strategy.

### *Embryonic Genome Editing*

Embryonic genomic editing targets the egg and sperm at the time of fertilization by co-injecting the sperm and the CRISPR/Cas9 editing complex into the egg. Because the

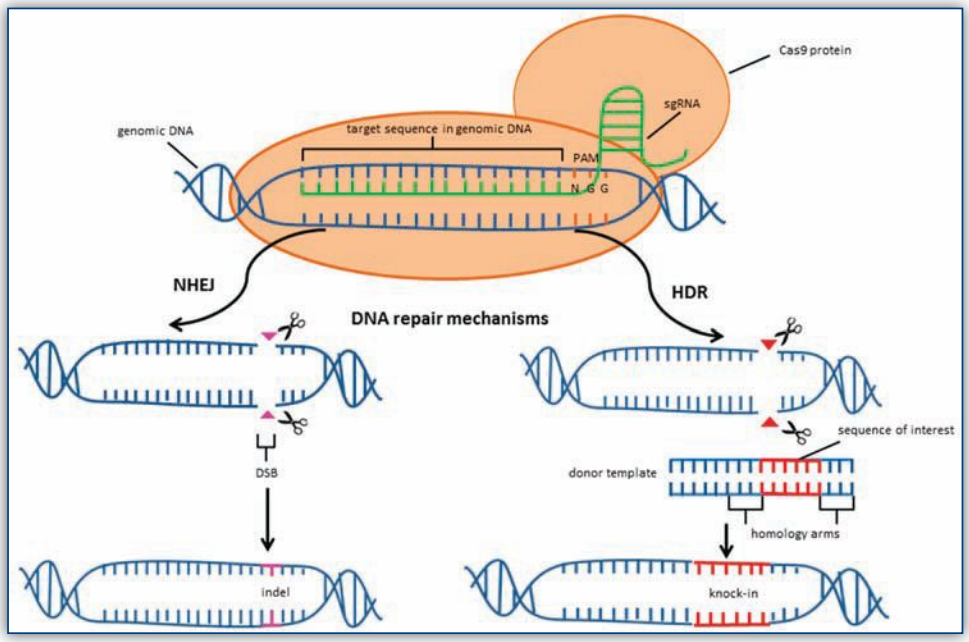


Figure 1. Cartoon representation of the CRISPR/Cas9 DNA cleavage mechanism. The large orange oval highlights the CRISPR guide RNA (green strand) bound to one strand of target DNA (blue strands) across 20 consecutive subunits, or nucleotides. The small orange oval behind it represents the Cas9 enzyme that cleaves both strands of the targeted DNA. The cellular fates of DNA cleaved by the CRISPR/Cas9 are depicted: (left) non-homologous end joining and (right) homology-directed DNA repair. From reference 17.

editing complex is delivered by injection, editing efficiency is relatively high and the challenges posed by somatic cell editing are avoided. Some fraction of edited cells will certainly populate the presumptive germ line, making the edited chromosome heritable and thus part of the human gene pool. Importantly, this includes not only the desired edits, but also any unintended off-target modifications that might have occurred and gone undetected.

Complicating the risk/benefit of clinical gene editing, some variants may be protective for some conditions while increasing risk for others. An example of this is a common sequence variant found at the SLC39A8 locus.[8] The SLC39A8 gene encodes a membrane protein that transports metal ions across cell membranes in various tissues, including the brain. An alanine-to-threonine variant at position 391 in the protein product of the gene is one of the few common variants implicated in schizophrenia susceptibility based on genome-wide association studies. However, other studies implicate the same variant in reduced risk for hypertension and Parkinson's disease.[8,9] Thus, the cost-benefit to gene editing for this variant is not straightforward. Given how little we know about the pleiotropic effects of most genes in the human genome, any genome edit that could enter the human gene pool should be evaluated with extreme caution.

## Ethics of Human Genome Editing

On November 28, 2017, Dr. He Jiankui, an associate professor at the Southern University of Science and Technology in Guandong China, shocked the audience at the Second International Summit on Human Genome Editing in Hong Kong by announcing the first babies — twin girls — born with CRISPR/Cas 9-edited genomes. The editing target in this case was the CCR5 gene, which encodes a cell surface receptor used by HIV to infect immune cells. The rationale was that the father was HIV-positive and that the girls might otherwise be born infected. By the next day, the organizing committee published a statement describing He's claim as "deeply disturbing," "irresponsible" and "failed to conform with international norms." The Chinese government ordered He to stop doing science and claimed that what He did was illegal under Chinese law.

Apart from the issue of legality, it appears that the project was unnecessary, as it is effective (and much cheaper) to wash sperm free of virus before insemination. Moreover, there is evidence that people with a naturally occurring mutation that inactivates the CCR5 gene are more susceptible to infectious and chronic diseases.[10] Finally, it isn't clear that the specific edit He used corresponds to a known naturally occurring mutation, so there may be unknown side effects. The critical importance of establishing internationally recognized rules and policies concerning acceptable uses of human germline editing and to harmonize regulations, in order to discourage unacceptable activities while advancing human health and welfare was underscored at the first international summit on gene editing, sponsored by the U.S. National Academies of Sciences, Engineering, and Medicine.[11]

**Table 1. Diseases that are candidates for somatic cell gene editing therapy**

| Disease | Affected gene | Clinical presentation | Prevalence |
|---|---|---|---|
| Alpha-1 antitripsin deficiency | *SERPINA1* | Lung and liver damage | ca. 1:1,500-3,500 in individuals of European ancestry |
| Amyloid transthyretin amyloidosis | *TTR* | problems with the nerves connecting the brain and spinal cord to muscles | 3-4% of African-Americans |
| Beta-thalassemia | *HBB* | Severe anemia | ca. 1:10,000 |
| Cystic fibrosis | *CFTR* | respiratory and digestive problems | ca. 1:2,500-3,500 Caucasians |
| Duchenne muscular dystrophy | *DMD* | Muscle weakness and damage | ca. 1:3,000 male births |
| Glycogen storage disease Ia | *G6PC* | problems with the liver, kidney and small intestine. | ca. 1:125,000 |
| Hemophilia types A and B | *F8* (type A)<br>*F9* (type B) | Failure of blood clotting | 1:4000-5000 (type A)<br>1:20,000 males (type B) |
| Huntington's disease | *HTT* | Severe progressive neurodegeneration, adult onset | ca. 1:14,000-33,000 individuals of European ancestry |
| Leber congenital amaurosis 10 | *CEP290* | hereditary childhood blindness | ca. 1:33,000-50,000 |
| Mucopolysaccharidosis types I and II | *IDUA (*type 1)<br>*IDS* (type 2) | Multiple tissue and organ damage | ca. 1:100,000 (type 1)<br>ca. 1:100,000 males (type 2) |
| Ornithine transcarbamylase deficiency | *OTC* | Development delay, intellectual disability, liver damage | Ca. 1:50,000-80,000 |
| Primary hyperoxaluria type 1 | *AGXT* | recurring kidney and bladder stones leading to kidney failure | ca. 1:72,000 |
| Retinitis pigmentosa | *NRL*<br>*NR2E3* | difficulty seeing at night and a loss of peripheral vision | ca. 1:3,500-4000 |
| Severe combined immunodeficiency | *IL2RG*<br>*JAK3*<br>*ZAP70* | ability to fight off bacterial, viral and fungal infections | ca. 1:50,000 |
| Sickle cell disease | *HBB* | Anemia, pain, organ damage | 1:500 African-Americans; ca. 1:1,000-1,400 Hispanic Americans |
| Sly syndrome (Mucopolysaccharidosis type VII) | *GUSB* | Affected growth and motor skills; mental retardation | Less than 1:250,000 |
| Tay-Sachs disease | *HEXA* | Progressive neurodegeneration | 1:3,600 people of Ashkenazi Jewish descent |
| Usher syndrome type 2a | *USH2A* | Progressive hearing and vision loss | ca. 1:10,000-100,000 |

*Adapted from refs. 7, 19 and 20.*

### *Ethics of Somatic Cell Genomic Editing*

The ethics of somatic cell genomic editing are, in principle, no more problematic than any therapy, as long as the proper testing for safety and efficacy is conducted. The consequences of somatic cell genomic editing are borne entirely by the patient and the edited genome dies with the patient. Under those circumstances, informed consent from the patient or their guardian would be sufficient to implement the therapy.

### *Ethics of Human Germ Line Cell Genome Editing*

Because human embryonic/germ line cell genome

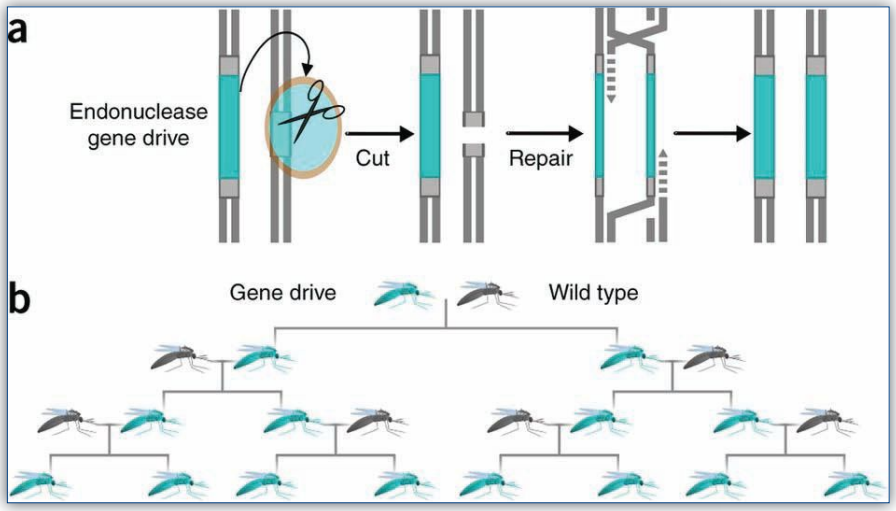


Figure 2. Mechanism and genetic transmission of CRISPR/Cas9-directed gene drives. (a) In an animal heterozygous for the gene drive CRISPR/Cas9 transgene, the Cas9 endonuclease (scissors) is targeted to the wild-type copy of the gene. When the cell repairs the resulting chromosome break using homologous recombination, it can use the gene drive chromosome as a repair template, thereby copying the drive onto the wild-type chromosome. (b) When a mosquito carrying the CRISPR/Cas9 endonuclease gene drive transgene (blue) mates with a wild-type mosquito (grey), the gene drive is preferentially inherited by most or all offspring. This can enable the drive-containing chromosome to spread over several generations until it is present in all members of the population. From ref. 18.

editing results in genome modifications that can enter the human gene pool, the ethical implications extend to our entire species. Thus, all of us are stakeholders in the future application of this technology. As illustrated by the swift and dramatic condemnation of Dr. He Jiankui discussed above, it is clear that human society is unwilling to extend blanket approval to the approach. Indeed, recent calls have been made for a moratorium on human germline genome editing (see below).

With the widespread use of *in vitro* fertilization and embryo selection, it is already possible for couples to choose a conceptus that is free from genetic disease. Accordingly, the cases in which germline editing is preferable to embryo selection are few.

### *Ethics of Human Genome Editing for Enhancement*

The most ethically problematic application for genome editing is for genome enhancement, the editing of the human genome with the goal of increasing traits such as, e.g., intelligence, strength, endurance or physical attractiveness. This application falls into the category of eugenics and is fraught with the question of whose values are reflected in a decision to valorize a particular trait. Furthermore, as with the cases of the SLC39A8 and CCR5 genes, the benefit being sought may be offset by negative effects.

## Other Applications of CRISPR/Cas9 Affecting Human Health

The potential for editing non-human genomes to advantage human health is huge. In addition to crop and livestock improvement, there is considerable interest in genome editing to eliminate the infectious diseases that have afflicted humanity for centuries.

For example, using CRISPR/Cas9 to modify the genomes of insect disease vectors to prevent disease transmission is a focus of research. In the case of malaria, promising results have been obtained for two strategies using CRISPR/Cas9 to (1) drive a mutation that causes recessive female sterility into the Anopheles mosquito population,[12] or (2) drive a mutation that makes the mosquito a poor vector for the malarial protozoan.[13,14] (Figure 2). In both reports, targeted transgene constructs carrying CRISPR/Cas9-based constructs result in >95% transmission of the mutant allele to progeny, where normal Mendelian inheritance would predict 50%. Unfortunately, neither of the reported strategies is yet ready for field-testing. Insects that carry a single copy of the CRISPR/Cas9 drive construct in each case are less genetically fit than wild-type mosquitoes, and thus the drive construct would be selected against in the wild. Further research is geared to making heterozygous transgenic mosquitoes at least as fit as wild-type mosquitoes. Also unknown is how likely it is that resistance to CRISPR/Cas9-based drive might appear, much like insecticide, herbicide, antibiotic and antiviral drug resistance arises over time. For example, variants in the CRISPR target sequences that make the targeting much less efficient will arise in large populations. Additionally, targets cleaved by Cas9 that are repaired by non-homologous end joining will result in a sequence immune to further CRISPR/Cas9 editing. These challenges may be addressed by using multiple CRISPR targeting RNAs in the drive construct.

Other examples of insect- or tick-borne diseases that would be amenable to CRISPR-Cas9 vector control include Chagas and Lyme disease, chikungunya, Dengue and yellow fever, leishmaniasis, trypanosomiasis, West Nile, and Zika.

While the public health benefit to interrupting the life cycle of human pathogens is obvious, there may be unintended consequences to driving specific insect species to extinction. Therefore, strict control of field trials is essential.

## Whither Genome Editing?

The genome editing genie is out of the bottle. Somatic cell genome editing is certain to become standard therapy for many inherited diseases, just as genetic modification of patient immune cells by CAR-T technology is moving into mainstream cancer therapy.

For germline genomic editing, the genie is also out of the bottle, despite the ethically fraught implication of eugenics. The *Homo sapiens* community will have to police the applications of germline genomic editing, since the human genome is ultimately the heritage of our species. The success or failure of germline editing regulation depends ultimately on the perception of "moral hazard," the idea that bad behavior can be constrained by awareness that the consequences are borne by everyone. Encouragingly, the moral hazard of nuclear proliferation, both for power generation and for nuclear weapons has achieved a shaky global comity that has held for over 70 years. However, the recent surge in vaccine resistance in the West is a cautionary counter-example, where misplaced fear of vaccine-related harm has broken the implicit societal compact of universal vaccination.

Recently, the journal *Nature* published a call from an international group of researchers and ethicists for a moratorium on the clinical application of human germline genome editing for up to five years.[8] The moratorium proposal has been endorsed by the U.S. National Academy of Sciences, the U.S. National Academy of Medicine, the U.K. Royal Society and the director of the National Institutes of Health.[15,16] During the moratorium period, the authors propose additional research on the safety of the technology and the development of an acceptable use policy. It is acknowledged that neither the moratorium nor any policies that emerge from it will be enforceable outside the borders of the nations that adopt them. What is certain is that the future will include human genome editing, with profound implications for our species.

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## Disclosure

None reported.

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