ST. LOUIS METROPOLITAN
MEDICINE
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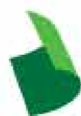

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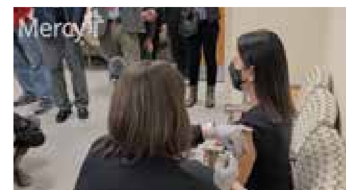
COVID Vaccine Arrives



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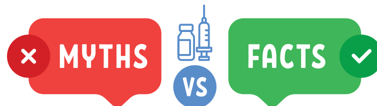

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CORRECTION: *In the article about physician alternative careers in the December-January issue of* St. Louis Metropolitan Medicine, *the late Dr. Armand Brodeur was incorrectly referred to as a pediatrician. He was a pediatric radiologist.*

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Trust. Advocacy. Membership.

Advocating for patients in 2021 with a strong SLMMS

Jennifer L. Page, MD, President, St. Louis Metropolitan Medical Society 2021

Jennifer L. Page, MD

In an era of uncertainty, myths and misinformation spread easily. We now play a critical role in helping end the pandemic by building confidence in the COVID-19 vaccine and the sound studies behind it.

Each new SLMMS president brings his or her past experience and passion to the role. I know that I have very big shoes to fill. I am honored to be president of an organization whose mission is to support and inspire member physicians to achieve quality medicine through advocacy, communication and education. I hope to bring a perspective of trust with that advocacy, with a goal to increase membership in the house of medicine.

I did not grow up thinking I had the possibility of becoming a doctor. I am a CODA (child of deaf adults). My two brothers and I grew up in a house where both our parents were deaf and our first language was sign language (ASL). Both of my parents were born with hearing, but each lost their hearing at a young age due to a febrile illness. They both grew up in low-income families that did not have access to health care; they met at the Missouri School for the Deaf. My mother, despite her impairment and limited education, was brilliant, and she did not delay with any illness. Any cough, cold or fever immediately warranted a visit to the pediatrician.

I had the good fortune, as did many children in the St. Louis area, of having Dr. George Sato[1]—longtime SLMMS member (1950-2013) and founder of St. Louis Pediatric Associates—as my pediatrician. As one of the hearing adults I met early in my lifetime, he was invested in my parents and their success in raising healthy children. He was invested in how I was maintaining my growth physically and emotionally, and he shared in my parents' excitement for my academic achievements.

Physician Leadership in COVID-19

Physicians are trusted by their patients and the public, and with that trust comes much responsibility. Our community looks to us to take care of them and give them sound science-based information. When we advise our patients and advocate for public policy, we ensure that these decisions are based on science and provide for the best possible care. The year 2020 has been historical, with the COVID pandemic highlighting the profound deleterious effects of racial disparity and access to health care. Misinformation wildly circulated about its treatments, and the lack of an early coordinated national response did little to prevent its spread.

COVID and its management quickly became politicized. If you asked someone to wear a mask, you were infringing on personal liberties. This was despite the fact that peer-reviewed articles elucidated how this virus was transmitted and showed how the public could control the spread and save lives and our community.[2]

Physicians were tasked with leadership roles. We set aside time to counsel and educate our patients. My disabled patients asked if they should wear a mask in public. My answer was a resounding "yes." When they asked, "Should I avoid traveling out of town to spend Thanksgiving with my extended family?" or, "Should I get the vaccine when it becomes available?" again I responded, "Yes."

The pandemic has shown the importance of disseminating factual information to the public. Physicians have become important in steering public health policy and advocating for our patients and our community. The St. Louis Metropolitan Pandemic Task Force[3] has been vital in providing information regarding transmission rates and hospital capacity, and it has helped steer public policy. In an era of uncertainty, myths and misinformation spread easily. We now play a critical role

in helping end the pandemic by building confidence in the COVID-19 vaccine and the sound studies behind it.

One of my highlights this socially distanced Halloween was seeing a child dressed as Jonas Salk, the virologist who developed the first successful polio vaccine. I did not see many traditional superheroes this Halloween—I saw first responder costumes. Similar to the increase in military enlistments after the September 11, 2001 attacks, today we are seeing "The Fauci effect." The number of applicants for medical school is up 18% this year over last year, according to the Association of American Medical Colleges (AAMC), driven by the example of medical workers and public health figures such as Dr. Anthony Fauci, director of the National Institute of Allergy and Infectious Diseases.[4] AAMC Senior Director Geoffrey Young labeled the interest as "unprecedented." Stanford University School of Medicine reports a 50% jump in the number of applications, or 11,000 applications for 90 seats. Boston University School of Medicine says applications are up 27%, to 12,024 for about 110 seats.[5]

The surge in COVID-19 hospitalizations has challenged the medical system and profoundly strained the physician workforce. However, even with these constraints, physicians still choose to organize.

Physicians are to publicly uphold and celebrate the ideals that have inspired individuals to enter medicine and earn society's trust in the healing profession. Item 8 of the American Medical Association's Declaration of Professional Responsibility states, *"Advocate for social, economic, educational and political changes that ameliorate suffering and contribute to human well-being."*[6] The preamble of the declaration also provides valuable guidance for today: *"Never in the history of human civilization has the well-being of each individual been so inextricably linked to that of every other. Plagues and pandemics respect no national borders in a world of global commerce and travel. … Today our profession must reaffirm its historical commitment to combat natural and man-made assaults on the health and well-being of humankind. Only by acting together across geographic and ideological divides can we overcome such powerful threats. Humanity is our patient."*[6]

St. Louis has been hit especially hard during the pandemic, and our physician community has stepped up to the challenge. SLMMS has been a strong advocate for COVID protective efforts of wearing a mask, education and public policy to flatten the curve.

SLMMS Priorities for 2021

My goal as president this year is to leverage the trust that physicians have earned through their years of education and experience to advocate for our patients and all people in our region. We should provide education and support for public policies that protect the health and welfare of our community.

- We must continue the fight to uphold the scope of practice for medicine that keeps our patients safe. There should be no confusion about who is qualified to lead health care teams and provide patient care, as this risks undermining the reliability of the health care system and puts our patients at risk.
- We must support Medicaid expansion. One of our SLMMS 2021 legislative priorities is to represent patient and physician interests in the expansion and the reforming of the state's Medicaid program so it is administered in an equitable fashion for all participants. Advocacy for equitable patient care is a vital step for the health of our community.
- To accomplish this, we must work to increase membership and promote the value of being part of such a vital organization as SLMMS.

> Together we will continue to earn the trust of our patients as we advocate for polices that protect them.

Joining SLMMS demonstrates you value professionalism and education and you recognize the role of a physician as an advocate and community leader. I recall riding in my parents' 1976 white Ford Torino, taking the long journey from north county to Barnes Hospital for my annual pediatric check-up. I was growing impatient. The windows were rolled down because there was no air conditioning in the car, and I was fed up. My dad was driving and I signed to my mom, questioning why we continued to take the long journey to see Dr. Sato. She replied, "Because I trust him."

Trust. Advocacy. Membership. I am honored to serve as your president in 2021, and together we will continue to earn the trust of our patients as we advocate for polices that protect them. Critical to achieving this is building and maintaining a strong and robust St. Louis Metropolitan Medical Society.

Jennifer L. Page, MD, is medical director of the Acute Rehab Program at Mercy Hospital South.

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SLMMS Continues Partnership with Keystone Mutual Insurance

In December, the St. Louis Metropolitan Medical Society renewed its approval of Missouri-based Keystone Mutual as the preferred provider of medical professional liability insurance for our members. Through this partnership, in place since 2012, SLMMS members receive a special benefit from Keystone in the form of a 10% discount on their medical malpractice premiums.

Keystone Mutual is the first Missouri-based medical professional liability insurance company to provide return of premium to policyholders upon retirement, death or disability. The company has experienced 13 consecutive years of growth, with an individualized customer focus to provide an outstanding policyholder experience.

Keystone Mutual's focus on open communication ensures physicians are prepared should an adverse situation arise.

The med-mal discount benefit has grown to become one of SLMMS' most popular member benefits. Nearly 150 SLMMS members are enrolled as Keystone clients. The benefit has also attracted close to 100 new members into the Society over the past eight years, including 21 new members in 2020, the most yet in a single year over the course of the partnership.

Dr. Jason Skyles

"I believe our members feel some security and confidence working with a high-quality organization based here in St. Louis," said Jason Skyles, MD, SLMMS immediate past president. "They also appreciate the protection Keystone offers them and its record of strong defense of claims."

"They continue to protect not just SLMMS members, but all Keystone clients, and offer sound risk management," added Dr. Skyles. "Along the way Keystone has also supported SLMMS programs and events. The trusted relationship between our organizations is a win-win for both."

Keystone is committed to its policyholders and partners, offering a wide variety of benefits, including its highly unique Keystone Capital Retirement Savings Program. The company also offers its clients choice of defense counsel if needed, and unlimited free legal advice if they have a risk management question. Keystone believes offering this service is the best way to mitigate risk, addressing risks proactively before they become an issue, thereby maintaining lower premiums for its policyholders.

Through their captive agency, Cogeris Insurance Group, LLC, Keystone offers comprehensive data security and privacy insurance covering physicians in the event of cyber threats or breeches, including extortion and multimedia liability. Medefense coverage protects policyholders in the event of Medicare or Medicaid billing audits and investigations.

Dr. C.B. Boswell

C.B. Boswell, MD, of Body Aesthetic Plastic Surgery and Skin Care Center and a SLMMS member since 2014, has been a Keystone Mutual client for a number of years. "It's been a good partnership," said Dr. Boswell. "The rates are very competitive and I feel comfortable with the malpractice and cyber coverage they provide for my practice and myself."

Keystone Mutual's focus on open communication ensures physicians are prepared should an adverse situation arise. The company has a conservative premium-to-surplus ratio, and is backed by more than $50 billion in reinsurance from trusted organizations such as AXA, Hannover, and Lloyd's of London.

Jim Bowlin

The renewal of the SLMMS-Keystone partnership is the third for two parties. "We are honored to have been again selected as the approved provider for such an outstanding organization," said Jim Bowlin, JD, Keystone's chairman and chief executive officer. "We take pride in protecting the reputations of the Society's physician members, and look forward to continuing our service to them for many years to come."

SLMMS MEMBERS

Learn more or request a quick quote by visiting keystonemutual.com/slmms/ or calling 866-212-2424.

SLMMS 2021 Legislative Priorities Adopted

The SLMMS Political Advocacy Committee met on December 9, 2020, with a primary goal of drafting the Medical Society's 2021 Legislative Priorities. Heidi Geisbuhler Sutherland, MSMA director of legislative affairs, joined the meeting and provided a preview of statewide initiatives and the upcoming 2021 Missouri legislative session.

The committee voted to retain most of the 2020 priorities, with modifications to initiatives addressing a statewide PDMP program, and revising the Medicaid expansion priority with respect to the results of the measure approved by voters last August. A timely addition to the list was a priority addressing COVID-19 liability, already a trending topic in the legislature.

Committee chair David L. Pohl, MD, presented the legislative priorities to the SLMMS Council on December 15, 2020. Following discussion, the Council voted to adopt the report that included the following:

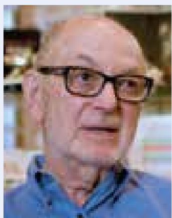
- Support legislative efforts to ensure that physicians who follow established COVID-19 guidelines and practice in good faith are protected from COVID-related professional and business liability.
- Promote coverage of drug addiction (including screening, prevention and treatment) by insurance providers as a medical condition, and encourage physicians to acquire greater understanding of the issues involved; support extending the St. Louis County Prescription Drug Monitoring Program (PDMP) statewide.
- Continue to oppose attempts by non-physicians to manage the practice of medicine, as well as support efforts that protect patients from misrepresentations by health care providers; seek clarification of the definition of surgery.
- Protect collaborative practice and the physician-led health care team approach to patient care.
- Concentrate on aspects of tort reform laws that remain to be addressed.
- Represent patient and physician interests in the expansion and reforming of the state's Medicaid program so that it is administered in an equitable fashion for all participants.

COVID-19 LIABILITY PROTECTION ADVANCES

A legislative proposal that would protect health care providers and others from liability during the COVID-19 emergency was passed by the Missouri Senate Judiciary Committee on January 25. It is now before the full Senate for approval.

SB 51, sponsored by Sen. Tony Luetkemeyer (R-Parkville), would protect health care workers from medical liability actions related to COVID-19 unless the plaintiff can prove that the action was caused by recklessness or willful misconduct resulting in injury. The legislation also contains product liability for manufacturers, designers and sellers. The bill has an emergency clause and would take effect immediately upon passage by both houses and signature by the governor. A similar bill in the House is HB 759.

Dr. Harry Knopf Receives Honor Membership Status



Harry L.S. Knopf, MD

At their December meeting, the SLMMS Council voted unanimously to grant honor membership status to **Harry L.S. Knopf, MD**. A Medical Society member since 1974, Dr. Knopf was recognized for contributing "Harry's Homilies" to each issue of *St. Louis Metropolitan Medicine* for over 25 years.

The Homilies, which first appeared in 1994, express positive thoughts and a lighter view of timely topics in medicine and the challenges physicians face. They provide a respite from the other serious content in the magazine. His messages always encourage readers to take the challenge in stride, and find a positive course of action. Member surveys over the years have indicated that the column has been one of readers' favorites.

In addition to contributing Harry's Homilies, Dr. Knopf has also served for many years on the SLMMS Publications Committee. He is an ophthalmologist retired from private practice and a part-time clinical professor at Washington University School of Medicine.

Along with the recognition, the SLMMS Council members expressed their wish that he will continue to inspire readers with his uplifting messages periodically throughout his retirement.

Q&A with SLMMS 2021 President Jennifer L. Page, MD

Tell us about your practice.

I am the medical director of the Acute Rehab Program at Mercy Hospital South and am board certified in physical medicine and rehabilitation and pain management. The Acute Rehab Unit at Mercy South treats patients with complex medical and rehab needs such as stroke, spinal cord injury or amputation that require inpatient hospitalization. Currently our unit is treating survivors of COVID complications including neuropathies, strokes and amputations.

Why did you choose to go into medicine? Why did you choose physical/rehabilitative medicine?

Growing up with two parents who were deaf, I always had an interest in medicine. Sign language (ASL) was my first language, and I was intimately aware of the impact of a disability on families. In medical school, I was a coach for Special Olympics and realized how much I enjoyed helping others reach their highest level of function, despite their impairments or disabilities.

What do you find most satisfying in practicing medicine?

Helping patients achieve their highest level of function despite their impairments and disabilities is very satisfying. I have an extended relationship with my patients; I get to learn their goals and help them achieve those. The goal may be returning to work, pursuing a favorite hobby, or the profound goal of being able to care for their children.

Tell us about your family.

I am married to Sam Page, MD, a member of SLMMS and the county executive for St. Louis County. We have three boys: Logan, who recently graduated from Washington University; Luke, a business major at the University of Arkansas; and Jake, a senior in high school. We have one dog, one snake and two backyard chickens.

What are your hobbies and interests outside of medicine?

I love spending time with my family, and try to spend as much time as I can outdoors hiking or kayaking at our farm. Pre-COVID, I loved to do jazz dance with my dance group. Like everyone, I am looking forward to a return to normal.

Both you and your husband, Dr. Sam Page, have been involved in politics, with you serving as a committeewoman. What do you find fulfilling about this activity? Why is it important for physicians to serve in elective office?

Every elected official brings their experience and education to their role in public office. Physicians have a unique opportunity to help guide public policy that can directly impact the health and welfare of the community. Key issues have included the prescription drug monitoring program, Medicaid expansion and the COVID-19 pandemic.

Continued on page 8

JENNIFER L. PAGE, MD

B.A. and M.D., University of Missouri-Kansas City

Internship, Mercy Hospital St. Louis

Chief Resident, Rush Presbyterian St. Luke's Medical Center, Chicago

The Page family from left: Logan, Dr. Jennifer Page, Dr. Sam Page, Luke and Jake.

Mercy congratulates Jennifer Page, MD, on being named the **2021 president of the St. Louis Metropolitan Medical Society**. Dr. Page is a pain management, physical medicine and rehabilitation specialist and medical director of acute rehabilitation at Mercy Hospital South. She continues to play a key role in the addition of a $37 million rehabilitation hospital on the Mercy Hospital South campus.

Dr. Page's leadership and contributions continue to improve our patients' mobility and quality of life. We applaud her selection as this year's president of the St. Louis Metropolitan Medical Society.

mercy.net/CongratsJennifer

Your life is our life's work.

President Q&A … *continued from page 6*

As our nation continues to navigate the COVID-19 pandemic and hopefully begins recovery in 2021, what do you see as the needs and concerns of physicians?

We must continue to advocate for patient safety and public policy that recognizes and addresses disparities in health care. Advocating for our patients requires us to protect the scope of practice for medical professionals. We need to support and promote legislation that allows us to maintain and build our medical practices.

What are your goals and priorities for SLMMS this year?

"Trust. Advocacy. Membership." is my theme. SLMMS should provide education and support for public policies that protect the health and welfare of our community. Examples include upholding the scope of practice for medicine that keeps our patients safe, and representing patient and physician interests in the expansion and reform of the Missouri Medicaid program.

To accomplish these goals, it is vital that we increase membership in SLMMS and promote the value of joining our Society.

What would you ask individual physicians to do this year to support the Medical Society?

Join SLMMS, renew your membership, and tell your colleagues about the value of membership. We must stand together to advocate for our patients. Our combined efforts can have a tremendous impact.

Is there anything else you would like to add?

Use your voice to give reason and science in explaining the benefits of vaccination to help our community and restore our economy post-COVID. Talk to your friends, neighbors and family about what you are doing to respond to the COVID-19 pandemic. There are still members of our community who are not fully engaged.

Annual Meeting Postponed Until January 2022

Out of an abundance of caution, the SLMMS Council has voted to cancel the 2021 Annual Meeting and Installation Dinner due to current COVID-19 circumstances. The meeting had already been postponed from January 30 to May 1. Now the Society will plan a combined 2021-2022 Annual Meeting for next January.

"This was a difficult decision as this is the largest event of the Society's year," explained Dave Nowak, SLMMS executive vice president. "But planning a May event requires preparing invitations and securing sponsorships in February, and current restrictions make that difficult if not impossible. There's still too much uncertainty planning a large event at this time. Pushing the banquet until later this summer or fall would run too close to the 2022 event. We will now plan to celebrate our incoming and outgoing leadership as well as our annual award winners at a combined event next year."

The proposed date for the combined event is Saturday, January 29, 2022, at the Living World at the Saint Louis Zoo. More information will be available later in the year.

SLMMS Recognizes 50-Year Members

The St. Louis Metropolitan Medical Society acknowledges 11 members who joined the Society in 1970 and achieved 50 years of continuous membership during the past year.

Normally these physicians would be recognized at the Annual Meeting and Installation Dinner. Since this year's banquet has been canceled due to COVID-19, they will receive their letters and certificates by mail.

Please join us in congratulating the following doctors for their membership and commitment to organized medicine:

- Jorge M. Alegre, MD
- Harvey E. Cantor, MD
- Horacio O. delRosario, MD
- Anson E. deVera, MD
- Ronald G. Evens, MD
- Gary Kulak, MD
- Roger L. Mell, MD
- Alejandro C. Ojascastro, MD
- Donald G. Sessions, MD
- Noel F. Weyerich, MD
- Tom M. Yazdi, MD

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COVID-19 Vaccine: Help Is on the Way

Vaccine availability brings joy and relief; next step is getting it into arms

By Jim Braibish, St. Louis Metropolitan Medicine

It was a joyous moment on December 14 when Aamina Akhtar, MD, infectious disease specialist and chief medical officer at Mercy Hospital South, received the first dose of COVID-19 vaccine administered in the St. Louis area. "The vaccine... it's that light at the end of the tunnel," Dr. Akhtar told KSDK-TV. "It's the best day we've had here in months, by far."[1]

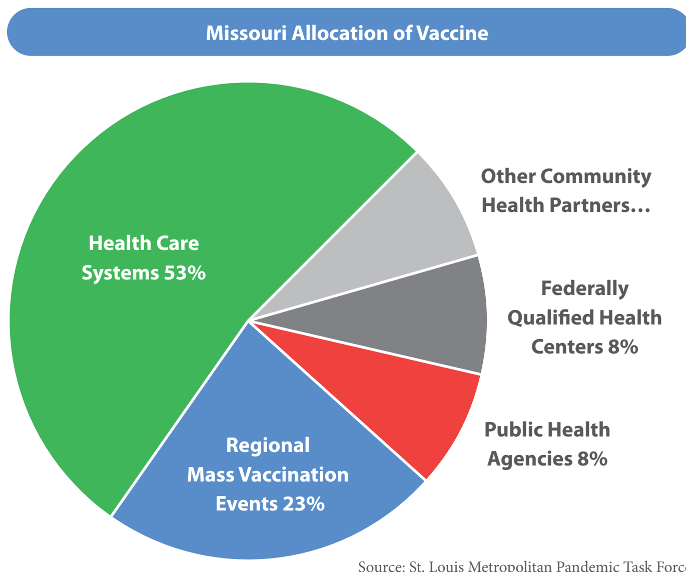
Now, two months later, we are into the hard work of vaccinating the largest number of people as quickly as possible. As of February 5, a total of 632,213 doses of the vaccine have been administered in Missouri, with 488,599 people receiving at least one dose.[2] In the St. Louis area, the four hospital systems that comprise the St. Louis Metropolitan Pandemic Task Force report that as of February 5, they have given 197,071 doses of the vaccine.[3]

Currently eligible to receive the vaccine in Missouri are health care workers, first responders, emergency personnel, persons age 65 and older, and persons with serious health conditions. This expansion, through Phase 1B, Tier 2, has been in effect since. Jan. 14.[4]

A major challenge is the shortage of vaccine supply relative to the eligible population, reported Alexander Garza, MD, in his February 5 briefing for the St. Louis Metropolitan Pandemic Task Force. There are currently about 700,000 people eligible to receive the vaccine in the 12-county region that includes St. Louis.[3] However, the CDC allocation for the entire state of Missouri for the week of February 1 is 76,000 for the Pfizer vaccine and 100,000 for Moderna, including first and second doses.[5] Of this, about half of the St. Louis-area vaccine supply is allocated to the large health systems, or 15,600 Pfizer doses per week.

Aamina Akhtar, MD, received the St. Louis area's first dose of COVID-19 vaccine before media and staff at Mercy Hospital South (Mercy).

Missouri Allocation of Vaccine



Source: St. Louis Metropolitan Pandemic Task Force

"If you do the math, you can see how long it's going to take us to reach this eligible population," Dr. Garza said, noting that the coming availability of the Johnson & Johnson vaccine will offer some relief.

To focus on the greatest needs, the health systems are focusing Phase 1B, Tier 2 vaccinations on persons over age 75 and those in active treatment for cancer or who have had solid organ transplants, Dr. Garza explained.

Types of Vaccines

The two COVID-19 vaccines currently in use, the Pfizer/BioNTech vaccine and the Moderna vaccine, are a new type of vaccine called messenger RNA (mRNA). These vaccines contain material from the SARS-CoV-2 virus that instructs our bodies on how to make a harmless protein. In turn, we build T-lymphocytes and B-lymphocytes that will remember how to fight the virus that causes COVID-19 if we are infected in the future.[6]

The other two main types of vaccines that are in development or undergoing Phase 3 clinical trials in the United States are protein subunit vaccines and vector vaccines. Protein subunit vaccines include harmless pieces (proteins) of the virus that cause COVID-19 instead of the entire germ. Vector vaccines contain a weakened version of a live virus—a different virus

than the one that causes COVID-19—that has genetic material from the virus that causes COVID-19 inserted in it.[6]

Of the vaccines next likely to be approved for use, the Johnson & Johnson and AstraZeneca vaccines are both viral vector.[7]

Information for Independent Physician Offices

During the initial vaccine rollout, independent physician offices and surgical centers were left wondering how they could get their patient-facing staff vaccinated, and when they could begin administering vaccines to patients. The St. Louis County Department of Public Health advises providers to visit www.stlcorona.com and click on the vaccine pre-registration link. The form includes a question about whether the individual is a health care provider. BJC HealthCare offers an email address that physician offices can use to be placed on a list to schedule vaccinations, BJC_COVIDVaccineforHCP@bjc.org.

Practices that would like to administer the COVID-19 vaccine should register with the Missouri Department of Health and Senior Services at http://bit.ly/movaccinator.

In a January 26 letter to President Joe Biden, the Medical Group Management Association called for physician offices to have a more prominent role in the COVID-19 vaccination effort. In a national MGMA survey the week of January 18, 85% of independent practices and 45% of health system-owned practices that sought COVID-19 vaccine for their patients report they were unable to obtain any.[8]

COVID-19 Variants

Multiple variants of SARS-CoV-2, the virus that causes COVID-19, have emerged in different parts of the world, and several of these have been documented in the United States. "Some of these variants appear to be associated with increased transmissibility, but to date there is no evidence these variants cause more severe disease than the original strain of SARS-CoV-2 that emerged in Wuhan in 2019, nor is there evidence they are associated with reduced vaccine efficacy or a reduced response to SARS-CoV-2 monoclonal antibody therapies," according to the Infectious Disease Society of America website as of January 29.[9]

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COVID-19 Vaccine Availability in Missouri

COVID-19 Vaccine Myths vs. Facts

Advice on responding to common falsehoods

With a host of misinformation about COVID-19 circulating on social media throughout the pandemic, it's not surprising that the availability of a vaccine is sparking a new round of falsehoods. Here are possible responses to popular myths you might hear from your patients, friends or family. The responses are excerpted and compiled from the "myth versus fact" web pages of Johns Hopkins University and the Mayo Clinic, supplemented by other sources.

Myth: The COVID-19 vaccine is not safe because it was rapidly developed and tested.

Fact: The COVID-19 vaccines from Pfizer/BioNTech and Moderna, the two approved so far, were created with mRNA technology that has been in development for years. Because of the urgency and seriousness of the pandemic, the U.S. government and other governments have devoted billions to vaccine development and research. The entire global scientific community has focused its attention on vaccine development; they also could draw on vaccine research done for previous SARS and MERS outbreaks. At the same time, the U.S. Food and Drug Administration is putting each vaccine candidate through its usual rigorous approval process which includes four phases of clinical trials involving tens of thousands of people; no shortcuts are being taken. Clinical trials for the Pfizer/BioNTech and Moderna vaccines have shown 95% effectiveness and minimal side effects.

Myth: There are severe side effects of the COVID-19 vaccines.

Fact: The COVID-19 vaccine can have side effects, but the vast majority are very short term—not serious or dangerous. The vaccine developers report that some people experience pain at the injection site, along with body aches, headaches or fever, lasting for a day or two. These are signs that the vaccine is working to stimulate your immune system as it was designed to.

Myth: Getting the COVID-19 vaccine gives you COVID-19.

Fact: The vaccine for COVID-19 cannot and will not give you COVID-19. The two authorized mRNA vaccines instruct your cells to reproduce a protein that is part of the SARS-CoV2 coronavirus, which helps your body recognize and fight the virus, if it comes along. The COVID-19 vaccine does not contain the SARS-CoV2 virus, so you cannot get COVID-19 from the vaccine. The protein that helps your immune system recognize and fight the virus does not cause infection of any sort.

Myth: COVID-19 vaccines will alter my DNA.

Fact: The first COVID-19 vaccines to reach the market are messenger RNA (mRNA) vaccines. According to the Centers for Disease Control, mRNA vaccines work by instructing cells in the body how to make a protein that triggers an immune response. Injecting mRNA into your body will not interact or do anything to the DNA of your cells. Human cells break down and get rid of the mRNA soon after they have finished using the instructions.

Myth: The COVID-19 vaccine was developed to control the general population through microchip tracking.

Fact: There is no vaccine microchip, and the vaccine will not track people or gather personal information into a database. This myth started after comments made by Bill Gates from The Gates Foundation about a digital certificate of vaccine records. The technology he was referencing is not a microchip, has not been implemented in any manner and is not tied to the development, testing or distribution of COVID-19 vaccines.

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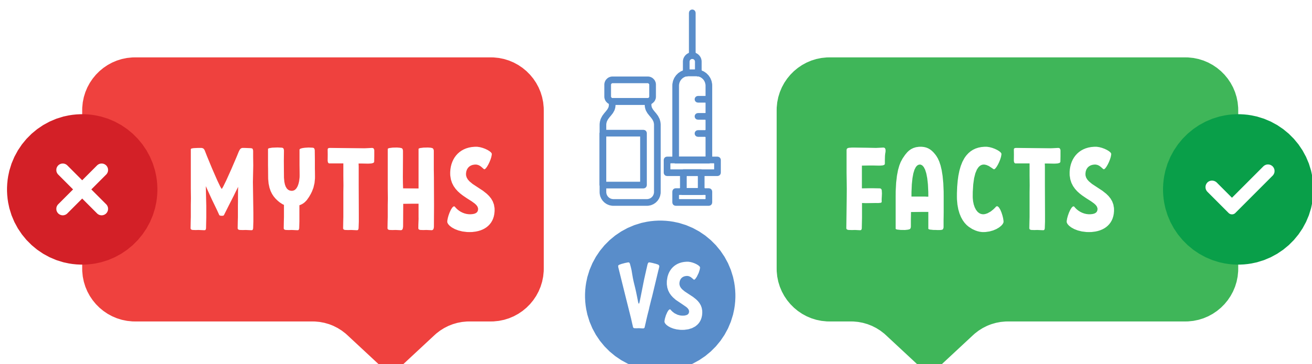

Convincing Blacks to Take the COVID-19 Vaccine Requires Overcoming Decades of Mistrust

By Jim Braibish, St. Louis Metropolitan Medicine

Local health care leaders recognize the challenge ahead of them in persuading African Americans to take the COVID-19 vaccine.

Early in the vaccination process, African Americans locally are receiving the vaccine at a lower rate than whites. Statewide in Missouri, 2.6% of Blacks have received the COVID-19 vaccine versus 6.9% of whites as of February 6, according to the Missouri Department of Health and Senior Services.[1] In a 12-county region including St. Louis, 8% of the vaccine doses administered through February 3 have been given to Blacks, according to the St. Louis Metropolitan Pandemic Task Force,[2] while their share of the population is 18%. Note, the St. Louis vaccination data is clouded by an 11% unknown rate.

Roots of Mistrust

The roots of African Americans' low rate of acceptance of the vaccine go back to several incidents of gross mistreatment of Blacks in health care research. In the 1930s, the U.S. Public Health Service began a 40-year study with the Tuskegee Institute that included 399 Black men with syphilis who were followed but never treated; and the study was conducted without the patients' informed consent. The other case most often cited is Henrietta Lacks, who unknowingly donated her cells to Johns Hopkins University in 1951, and whose cells continue to be used in medical research.

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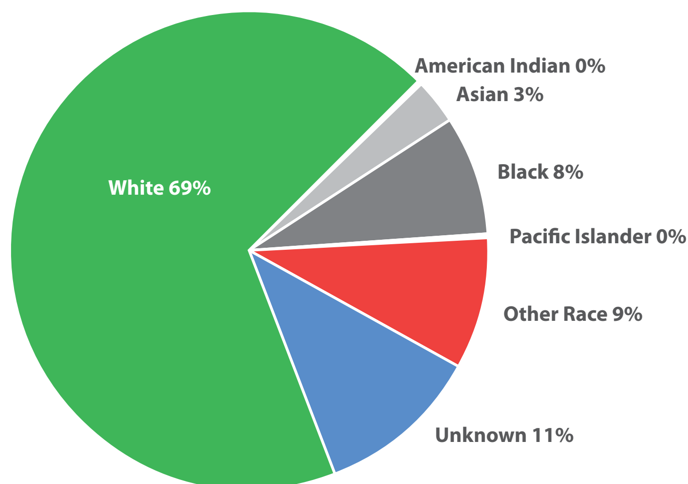
"Look at the history of what happened, and our patients don't forget the mistreatment. It's incumbent on us as health providers to constantly work to rebuild that trust," said Denise Hooks-Anderson, MD, assistant dean for diversity, equity and inclusion at Saint Louis University School of Medicine, in a February 2 vaccine webinar. Presented by the medical school Office of Diversity, Equity and Inclusion, the February 2 webinar primarily targeted Black individuals and featured Black physicians.

Vaccine Doses Administered in the St. Louis Region by Race

Of 197,071 total doses administered as of February 5, 2021



Source: St. Louis Metropolitan Pandemic Task Force

Another speaker on the webinar was infectious disease specialist and SLMMS Councilor Otha Myles, MD. He added, "Whenever I go out and speak about vaccines, I get asked about Tuskegee. … We have to acknowledge that those things did happen and explain that things are different today."

He continued, "I'm really encouraged that the lead scientist at NIAID on the mRNA vaccine is an African American woman, Kizzmekia Corbett. Those are the kind of things that we have to push. That we are working together with the government, with other institutions, so we are watching what is happening in our community, so there is someone they can trust."

Dr. Myles also noted African Americans' higher participation in the vaccine clinical trials than in previous trials. Over 7,000 Blacks have participated in the Pfizer and Moderna clinical trials, representing about 10% of the subjects, according to the CDC.[3]

Prioritizing Vaccine Equity

Area leaders emphasized the priority being given to equity in vaccine distribution.

A spokesperson for BJC HealthCare said, "We are sensitive to vaccine reluctance within the African American community and the need for the medical establishment to establish trust. … We are working with area federally qualified health centers including Affina, CareSTL and others to support community vaccination efforts, and actively partnering

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This article is provided through the Medical Society's partnership with Greater St. Louis Medical Group Management Association, www.mgmastl.org

Legal Protections for Medical Practices Administering COVID-19 Vaccine

By Kevin K. Peek, JD

In December 2020, the U.S. Food and Drug Administration (FDA) issued an emergency use authorization (EUA) for a vaccine for the prevention of COVID-19. While this is different than an FDA approval, the EUA was based on sound scientific evidence and study. It allowed for rapid and widespread deployment of the vaccine.

Despite the EUA, some of the public expressed concerns regarding the effectiveness and safety of the vaccination. News stories even hinting at side effects from the vaccine spread like wildfire, further fanning existing doubts and potentially creating arbitrary grounds for malpractice lawsuits. Alternately, individuals are bringing legal challenges to state allocation plans, arguing that denial of access to the vaccine immediately is a violation of rights under the U.S. Constitution.[1]

Given such circumstances, should medical providers be concerned about being dragged into legal proceedings by administering available COVID-19 vaccinations over these next several months? Generally, not really.

Protection of Health Care Workers

On March 10, 2020, the Secretary of Health and Human Services issued a declaration of liability protection under the PREP Act, protecting licensed health professionals, manufacturers, distributors, program planners, and those that prescribe, administer or dispense drugs, biological products or devices used to diagnose, mitigate, prevent or treat COVID-19.[2] The declaration protects from liability under federal and state law for "any type of loss" relating to administration of covered countermeasures. Willful misconduct is not covered by the declaration. Health care workers can confidently administer vaccinations with these protections in place.

Remedies for Vaccine Recipients

The National Vaccine Injury Compensation Program (VICP) provides compensation for injuries caused by routinely administered vaccinations.[3] It is a no-fault system of compensation for vaccine-related injuries proven to be caused by vaccines. This system favors plaintiffs (patients) as it has a lower burden of proof. However, the VICP does not cover COVID-19 vaccinations.

> The programs and controlling declarations in effect should ease concerns regarding administration of the COVID-19 vaccinations. Health care providers are protected, and recipients of the vaccine have a remedy.

Instead, such vaccinations are covered by a different system to compensate those who experience any rare, serious adverse reactions to the vaccine. The Countermeasures Injury Compensation Program (CICP)[4] provides reimbursement of reasonable medical expenses, or loss of income or survivor benefits for individuals seriously injured or killed by countermeasures. Countermeasures include not only vaccinations, but also medication, devices or other items recommended to diagnose, prevent or treat declared pandemic or security threats. The seasonal influenzas vaccine is not covered by CICP but would be covered under VICP. Once HHS makes a decision under CICP, a party can seek a reconsideration but cannot seek a judicial appeal. This differs from VICP in which judicial appeals are allowed.

Kevin K. Peek

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It is undeniable that the development and initial distributions of a vaccination to the pandemic-causing COVID-19 within one year of its onset is an extraordinary achievement of science, medicine and collective cooperation. With the U.S. death toll now exceeding 400,000,[5] efficient distribution channels and navigation around avoidable roadblocks (legal, physical, and disinformation-based) are of great importance. The programs and controlling declarations in effect should ease concerns regarding administration of the COVID-19 vaccinations. Health care providers are protected, and recipients of the vaccine have a remedy in the highly unlikely and rare event that a severe injury as a result of the vaccination is experienced.

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Convincing Blacks … *continued from page 13*

with the Regional Response Team, PrepareSTL and other community organizations to connect medical experts with community champions and to amplify empathetic and accurate information regarding vaccination. Our goal is to stay engaged and provide easy access to vaccine for the African American community."

At the St. Louis County Department of Public Health, acting co-director and SLMMS Councilor Emily Doucette, MD, commented, "Our mission is to maintain and improve the health of our county, with particular attention paid to those who have been historically underserved or are especially vulnerable. We are diligently working with our community partners and other organizations to make sure that the vaccine is offered in multiple locations throughout the county—especially in areas that might not otherwise have equitable access to vaccine care.

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Commentary

Choice, Lived Experience and Trust: Opportunities With the Rollout of the COVID-19 Vaccine

Coming together as a community plays out differently depending on population and history

Reprinted with permission from Missouri Foundation for Health, published in MFH's blog on January 28, 2021, as "My Take on the COVID Vaccine: Choice, Lived Experience and Trust"

By Bob Hughes, PhD

In 2021 all Missourians are participating, one way or another, in a life-and-death undertaking to bring the pandemic under control by reaching herd immunity as soon as possible. How quickly we reach that goal depends on how well public agencies, nonprofit health care organizations and private entities can come together to effectively distribute and administer vaccines, and the extent to which Missourians choose to get vaccinated for COVID-19. The challenges to supplying and administering the vaccine into millions of individual arms across the nation are well documented. I'd like to explore the factors that influence Missourians' choices to get the vaccine.

Let me begin by telling you my view: I encourage everyone to get vaccinated, including my family. I look forward to getting vaccinated when I am eligible. Several members of my family who are involved in patient care have gotten both doses of the vaccine and have had no ill effects, but I appreciate that everyone comes to the decision about getting the vaccine by exercising their freedom of choice, much of which is based on their lived experiences. These differences matter.

Each of us has different health circumstances, risk factors and experiences with the health care system. The information overload that bombards Missourians every day – some of it incorrect and even intentionally misleading – can make reaching a decision hard. There are legitimate questions about the vaccine, many of which we don't know the answers to, that will need more time, planning and analysis before we can have greater certainty. How quickly will the vaccines be available to the groups as the various tiers are rolled out? When will new vaccines be approved? How long will vaccines be effective for most people? Then, there are questions about the supply. Are we going to run out of vaccine before I can get it? Where do I go to get vaccinated? Will my entire household be able to get vaccinated when my time comes? Why is Missouri doing so poorly at vaccine distribution?

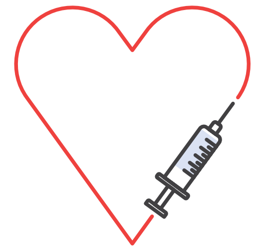
We need to acknowledge how the histories and experiences of all Missouri communities will shape decisions about the vaccine and work to build trust so that our state is successful in taking care of its residents.

A forthright acknowledgement that the processes of producing, distributing and administering the vaccine are changing will begin to establish public understanding and acceptance. Officials need to reinforce that the science itself is ongoing and as more is learned and understood, that information will be shared transparently. As we know with science, we don't have all the answers right away, and that's okay. There's no need to fill in gaps with misinformation or answers that are not accurate.

Dr. Bob Hughes

Bob Hughes, PhD, is president and CEO of Missouri Foundation for Health, which is dedicated to improving the health of Missourians through partnership, experience, knowledge and funding.

A forthright acknowledgement that the processes of producing, distributing and administering the vaccine are changing will begin to establish public understanding and acceptance. Officials need to reinforce that the science itself is ongoing and as more is learned and understood, that information will be shared transparently.



A simple, "We don't know," sets expectations, and above all, it's factual. This approach is essential to building trust between those involved in the work and the Missourians who will be making the decision to get vaccinated.

This period of vaccine distribution can present various opportunities, and as a state, we should be thinking about how our approach to this process will best benefit the people. First, Missourians need clear, honest information if we are to make the best choice for our families. It will be especially challenging for officials to build trust with people and communities that have experienced a history of neglect, deception, lies and mistreatment. This includes rural residents who have been underserved as they've seen hospitals close and inpatient care access decline; as well as the Black community with memories of the Tuskegee Study of untreated syphilis in Black men, the Henrietta Lacks wrongdoings, and stark racial health inequities that persist into the present day, as reflected in COVID-19's impact. In brief, we need to acknowledge how the histories and experiences of all Missouri communities will shape decisions about the vaccine and work to build trust so that our state is successful in taking care of its residents.

As we work collectively toward herd immunity, the experiences of the early vaccine recipients will reassure those seeking additional insights into how the vaccine is working. It's not uncommon for people to be moved to action based on the experiences of others in their circles, those close to them. Social networks in communities establish and spread shared perspectives, so the voices of trusted leaders and early adopters play an important role in helping others overcome hesitancy and understanding the progress being made. As communities learn from experience, they will reinforce the benefits for others. Early results of our own vaccine research on attitudes and perceptions of Missourians underscore that people want to hear from their own.

There are many personal reasons to get vaccinated—protection from COVID-19, getting back to "normal," being able to hug family members. But getting vaccinated isn't just about protecting yourself; it is about protecting those around you. Reaching herd immunity requires that the vast majority of us get vaccinated (or rely on protection by becoming infected, risking suffering and death) to protect society as a whole. It is my hope that we can mobilize in good faith to make real progress quickly, and thereby lay the foundation for more positive, broad-based advances in our collective well-being in the future.

Local Resources Contribute to Vaccine Development and Trials

St. Louis has made important contributions in the development and clinical trials of the COVID-19 vaccines.

Pfizer

The Pfizer facility in Chesterfield is manufacturing plasmid DNA for the vaccine antigen. The template DNA is manufactured in a cell culture process and subsequently purified through a series of chromatographic and filtration steps. The purified template DNA is then linearized in preparation for the manufacture of the mRNA drug substance at Pfizer's Andover, Mass., facility.

Saint Louis University

SLU's Center for Vaccine Development enrolled participants in the Moderna and Janssen Pharmaceutical Companies (Johnson & Johnson) Phase 3 clinical trials to study the effectiveness, safety and immune response generated by the vaccines. SLU also is a part of the National Institutes of Health (NIH) ongoing trial for remdesivir. SLU is one of only 10 institutions selected by the NIH as a Vaccine and Treatment Evaluation Unit. Daniel Hoft, MD, PhD, leads the VTEU as principal investigator, and is a voting member of the National Vaccine Advisory Committee of the U.S. Office of Infectious Disease Policy and HIV/AIDS. Sharon Frey, MD, clinical director of SLU's Center for Vaccine Development, sits on the CDC's Advisory Committee on Immunization Practices.

Washington University

The School of Medicine at Washington University has enrolled participants for the Janssen study and is studying long-term immune response among a cohort of 175 recovered COVID-19 patients. The school also is conducting trials for remdesivir and monoclonal antibodies, and is monitoring for vaccinated health care workers who contract COVID. Hilary Babcock, MD, MPH, assistant professor, is co-chair of the CDC Healthcare Infection Control Practices Advisory Committee.

HIPAA Guidance During COVID-19

HHS clarifies how patient information may be shared with public health authorities via electronic health information exchanges while the emergency is in effect

By Denise Bloch, JD

The COVID-19 public health emergency continues to provide many challenges for health care providers. One such challenge concerns how HIPAA impacts providers and their business associates disclosing protected health information via electronic health information exchanges for reporting to a public health authority. Examples might include COVID-19 test results, contact tracing and vaccines administered. On December 18, 2020, the Office for Civil Rights (OCR) published guidance[1] to help answer the questions that health care providers and their business associates face on this subject.

These answers will help navigate the maze of issues related to how providers use and disclose protected health information via these electronic information exchanges to respond to the many facets of the COVID-19 public health emergency. The current federal emergency declaration is now set to continue for another 90 days from the latest renewal on January 7, 2021.[2]

It will continue to be important that all health care staff understand HIPAA and how to protect PHI.

1. What is a health information exchange (HIE)?

Despite the growth of electronic health records, it is still commonplace for a patient's records to be spread across many different providers, from the local pharmacy to the primary care doctor to one or more specialists. Health information exchanges (HIEs) allow different providers to access and securely share a patient's medical information electronically, providing necessary care coordination and improving the speed, quality and safety of patient care. During the pandemic, HIEs have played an important role in aggregating public health data and providing key alerts to public health officials. HIEs may be nationwide as well as statewide HIEs, regional health information organizations (RHIOs) and some clinical data registries.

2. When does HIPAA permit a provider to disclose protected health information (PHI) electronically to an HIE for purposes of reporting to the public health authority, without an individual's authorization?

During the health care emergency, the importance of sharing data to improve public health has been an important issue. HIPAA permits covered entities and their business associates to share PHI with an HIE for reporting to a public health authority conducting public health activities for the following circumstances:

- The disclosure is required by law.[3]
  - For example, a state law requires reporting patient treatment and laboratory testing data to an HIE in order for the HIE to report the data to the appropriate local or state health department. Such disclosure would not violate HIPAA.
- When the HIE is a business associate of the provider that desires to provide information for public health purposes.
  - For example, the provider or its business associate may have the HIE, as its business associate, provide information on its behalf for a HIPAA-covered function, such as treatment or other permitted purpose that may include public health uses and disclosures.
  - Any disclosure of PHI would be subject to the terms of the business associate agreement between the HIE and the provider or its business associate, except when PHI is transmitted in response to a public health authority's request during the COVID-19 emergency; even without an agreement, the transmission is allowed.
- When the HIE is acting under a grant of authority or contract with a public health authority.[4]

Denise Bloch

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3. **Can a provider rely on a public health authority's request to disclose a summary record to an authority or HIE as being the minimum necessary PHI needed by the authority to accomplish the public purpose of the disclosure?**

Yes. The provider's disclosure of a summary record should be limited to the minimum necessary to achieve the purpose of the disclosure. If the public health authority represents that the request is the minimum necessary to accomplish its stated public purpose,[5] the provider may rely on the request as being reasonable.

4. **May a provider disclose PHI to a public health authority through an HIE without receiving a direct request from the authority?**

Yes. A direct request for PHI from the public health authority is not required to allow for disclosure by the provider through an HIE to the public health authority.

- A public health authority, i.e. the county health department, is authorized to obtain COVID-19 test results. The authority may utilize an HIE to obtain summary records of COVID-19 test results from local health care providers. If the provider knows the authority is using the HIE to collect information on its behalf, the provider may disclose the information to the HIE even if it does not receive the request directly from the authority.

5. **May an HIE provide PHI it has received as a business associate of a provider to a public health authority for public purposes without first obtaining permission from the provider?**

Yes. During the COVID-19 public health emergency, the OCR issued a notice of enforcement[6] stating it will take no action against a business associate for making PHI disclosures in good faith for public health purposes even if the agreement between the provider and the business associate does not expressly permit disclosure of PHI from the business associate to a public health authority. However, in these cases, the business associate must inform the provider within 10 calendar days after the use or disclosure.

6. **Is a provider required to provide notice to individuals about its disclosures of PHI to a public health authority for public health purposes? Is an HIE that is a business associate required to provide such notice?**

Yes. The provider is required to provide notice to individuals, in the provider's Notice of Privacy Practices (NPP), that it discloses PHI for public health purposes.[7] As a result, individuals receive advance notice through the NPP of potential uses or disclosures of their PHI that may occur without the individual's authorization.[8] However, HIPAA does not require disclosure of PHI to a public health authority. As a result, a provider may honor an individual's request that the individual's PHI not be disclosed to a public health authority, unless otherwise required by law.

Business associates, including HIEs, are not required by HIPAA to provide a NPP to individuals. However, the provider is required to provide an accounting of disclosures of an individual's PHI upon request, including disclosures made for public health purposes.[9] In certain circumstances, the business associate may be directly liable for failing to provide an accounting of its disclosures of PHI, which may include disclosures for public health purposes.[10]

Conclusion

Since PHI may be disclosed to HIEs for public health purposes without first obtaining authorization from the individuals, individuals must receive notification of these possible disclosures. As a result, it is important that potential disclosures for public health purposes are included in covered entities' NPP. Throughout the COVID-19 health care emergency and with the onset of the vaccinations, questions will continue to arise regarding HIPAA and how to protect patient PHI. The Privacy Rule allows access to information needed to protect the public while protecting the privacy of individual patients' PHI. It will continue to be important that all health care staff understand HIPAA and how to protect PHI. Reviewing your policies and procedures related to HIPAA, PHI and privacy will help to ensure that they address sharing of PHI with HIEs for public health purposes.

When questions arise about the propriety of disclosures of PHI, i.e. to an HIE for public health purposes or concerning other HIPAA questions, legal counsel may assist physicians to obtain answers to those questions. A review of HIPAA compliance policies may also be helpful to ensure that policies and procedures are compliant with the current COVID-19 public health emergency. Finally, annual HIPAA training helps keep staff and providers aware of their obligations under the Privacy Rule.

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4. *See* 45 CFR § 164.501 (definition of "public health authority;" *see also* 45 CFR § 164.512(b) (description of public health activities).
5. *See* 45 CFR 164.514(d)(3)(iii)(A). *See also* OCR, FAQs on Minimum Necessary, at https://www.hhs.gov/hipaa/forprofessionals/faq/minimum-necessary/index.html.
6. As stated in the published notification, "the [Business Associate NED] will remain in effect until the Secretary of HHS declares that the public health emergency no longer exists, or upon the expiration date of the declared public health emergency (as determined by 42 U.S.C. 247d), whichever occurs first." See 85 FR 19392 (April 7, 2020) available at https://www.govinfo.gov/content/pkg/FR-2020-04-07/pdf/2020-07268.pdf.
7. *See* 45 CFR 164.520(b)(1)(ii); 45 CFR 164.512(b)(1)(i).
8. *See* 45 CFR 164.520(c)(3)(i).
9. *See* 45 CFR 164.528. This general requirement to account for disclosures of PHI does not apply to disclosures of a limited data set for public health purposes pursuant to 45 CFR 164.514(e). See 45 CFR 164.528(a)(1)(viii).
10. See the HITECH Act section 13405(c)(3), 42 U.S.C. 17935(c)(3).

New Law Brings Necessary Clarity to Punitive Damages in Missouri

Health care providers are less likely to face harsh judgments

By John F. Mahon, Jr., JD

Punitive damage reform, Senate Bill 591, was signed into law by Missouri Gov. Mike Parson on July 1 of last year and applies to all lawsuits filed on or after August 28, 2020. SB 591 makes significant changes to the framework for punitive damages in tort actions filed in Missouri state courts or filed in other courts but based on Missouri state law tort claims. This is important for health care providers because the new law applies to medical malpractice cases.

The discussion that follows focuses solely on medical malpractice cases and potential benefits the new law may afford to health care providers. Though not dealt with here, SB 591 also includes significant changes to actions under Missouri's consumer protection statute, the Merchandising Practices Act.[1]

Clarifying the Proper Standard

SB 591 is intended to bring much-needed clarity to the standard for imposing punitive damages against health care providers. Punitive damages are different than compensatory damages in that they are designed not to compensate an injured party for actual losses, but to punish or deter misconduct that goes beyond mere error and into the realm of intentional harm. Thus, the focus is not on the nature and extent of the injury to the patient, but on the circumstances surrounding the health care provider's misconduct. This issue is of particular significance to health care providers because, due to the intentional nature of the misconduct, professional liability insurance policies often do not cover punitive damages or specifically exclude them from coverage. This can leave an individual physician without insurance coverage and vulnerable to judgment against personal financial assets.

The Missouri Legislature previously addressed punitive damages in 1986. Since then, Chapter 538 of the Missouri Revised Statutes has included a definition for punitive damages that describes them as those "**intended to punish or deter willful, wanton or malicious misconduct.**"[2] Consistent with this definition, the legislature intended that punitive damages may be awarded against a health care provider only "**upon a showing by a plaintiff that the health care provider demonstrated willful, wanton or malicious misconduct … .**[3] Unfortunately, as we shall see, this statutory definition has proved problematic in its application and caused much confusion for health care providers and the courts.

For example, *Koon v. Walden*, is a 2017 Missouri medical negligence case that involved allegations of over-prescription of opioid pain medication, resulting in a substantial $15 million punitive damages award. In that case, the trial court approved—over the defendants' objection—a jury instruction submitted by the plaintiffs that used the lesser standard "complete indifference or conscious disregard" (for the patient's safety) instead of the "willful, wanton or malicious misconduct" standard mandated by § 538.210.8.[4] Because the trial court allowed the lesser standard, the jury was never instructed to use the statutory language, and did not actually find that the defendants engaged in "willful, wanton or malicious misconduct."

The Missouri Court of Appeals, Eastern District, refused to overturn the verdict, concluding that for purposes of punitive damages, acting with "complete indifference or conscious disregard for the safety of others" is the legal equivalent of engaging in "willful, wanton or malicious misconduct."[5] In a concurring opinion, one Court of Appeals judge stated: "I agree that the common understanding of the words 'willful, wanton or malicious' mean something different than 'complete indifference to or conscious disregard for the safety of others,'" and that the Missouri Supreme Court should review and decide the issue.[6]

Unfortunately, despite this invitation from one of the judges, the state Supreme Court denied the health care providers' application for transfer and refused to consider the issue. That meant that the jury's large punitive damage award remained intact, even though the Missouri high court did not review the merits of the case whatsoever.

John F. Mahon, Jr.

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Fortunately for health care providers, SB 591 tackles this issue head on. It requires that a jury find "**the evidence clearly and convincingly demonstrated that the health care provider intentionally caused damage to the plaintiff or demonstrated malicious misconduct that caused damage to the plaintiff**."[7] Further, and apparently in direct response to the controversial Koon decision, SB 591 explicitly states that: "**Evidence of negligence including, but not limited to, indifference to or conscious disregard for the safety of others shall not constitute intentional conduct or malicious misconduct.**"[7]

This important change reflects a return to the original common-law standard of punitive damages being reserved for intentional misconduct. It represents the legislature's effort to clarify for the courts the proper legal standard and prohibit continued use of lesser standards like the one the court allowed in *Koon v. Walden*.

As mentioned above, as part of this new, heightened standard, SB 591 includes the "clear and convincing" burden of proof for punitive damages. This concept is not new, however, as the Missouri Supreme Court adopted this evidentiary standard for all tort cases in the 1996 decision *Rodriguez v. Suzuki Motor Corp.*[8] Now, SB 591 codifies this standard into the statutory framework for punitive damages.

Unchanged is § 510.265, RSMo. (2005), which continues to cap punitive damages in most civil cases by limiting them to $500,000, or five times the net amount of the judgment awarded to the plaintiff, whichever is greater. The 2014 *Lewellen v. Franklin* decision—in which the Missouri Supreme Court reasoned that applying the punitive damages cap to a common law cause of action violated the constitutional right to a trial by jury—does not prohibit the legislature from limiting damages in statutory actions such as medical negligence cases.[9]

Significant Procedural Hurdles

Though not solely applicable to medical negligence lawsuits, SB 591 also includes a series of procedural hurdles that a plaintiff must overcome before a court may allow a plaintiff to assert a claim for punitive damages and submit such a claim to a jury. These changes are found in Chapter 510 of the Revised Missouri Statutes. Under the new law, a plaintiff is not permitted to assert a claim for punitive damages until after a court has determined, based on available evidence, that a jury could reasonably conclude there is "clear and convincing" evidence that the health care provider "intentionally caused damage" or committed "malicious misconduct."[10]

This will be an important procedural requirement, as it has become increasingly common for Missouri plaintiff attorneys to include in every medical negligence petition a prayer for punitive damages, along with compensatory damages, as a matter of routine no matter the type of case or nature of the facts. This questionable practice should no longer be tolerated, unless the court grants a properly supported motion filed no later than 120 days before the final pretrial conference or trial. No pleading or discovery of any kind shall be permitted on punitive damages, unless a plaintiff first clears this procedural hurdle. This should help remove the specter of punitive damages from cases where they are not appropriate (which are the vast majority of medical negligence cases) and reduce litigation costs and privacy invasion associated with unnecessary discovery into a health care provider defendant's financial net worth.

Vicarious Liability Issues

SB 591 also includes a "Complicity Rule" that limits vicarious liability for punitive damages against an employer/principal for employee/agent misconduct. The new law permits such an award against an employer for the conduct of an employee only if the employee was a managerial employee acting in the course and scope of his employment; the employer authorized or later ratified the employee's conduct; or the employee was "unfit" for the job making it "reckless" for the employer to hire or retain the employee.[11] It remains to be seen how courts will apply this rule to corporate entities that employ health care providers, but § 538.210.4, RSMo. (2017) is unchanged and continues to prohibit health care provider vicarious liability for the conduct of a non-employee agent.

Conclusion

SB 591 represents a significant benefit to health care providers by returning to the original common law concept of intentional misconduct being a prerequisite for an award of punitive damages. It is a robust effort designed to bring into focus the blurred line between mere negligent conduct and conduct that justifies an award of punitive damages, along with a procedural framework to weed out frivolous claims and ensure plaintiffs are held to the appropriate standard and burden of proof. The provisions outlined above appear to offer significant protections for health care provider defendants, while also allowing for the possibility of a punitive damages claim, but only in the rare circumstance where the evidence would support it.

Editor's Note: The Missouri State Medical Association, supported by SLMMS member physicians and other physicians around the state, played a significant role in advocating for SB 591.

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10. § 510.261.5, RSMo. (2020).
11. § 510.261.3, RSMo. (2020).

Myths vs. Facts … continued from page 12

Myth: The COVID-19 vaccines were not tested among minority groups so we don't know if the vaccines are safe for them.

Fact: Developers of the vaccines are making great effort to recruit African Americans, Hispanics and other minorities to the clinical trials and overcome past under-representation. Nearly 7,000 African Americans and 16,000 Hispanics have participated in the trials for these two vaccines. Pfizer/BioNTech and Moderna each report that 10% of their trial participants were Black, compared to 12% of the U.S. population. For Hispanics, while they represent 18% of the population, they comprised 26% of Pfizer trial participants and 20% of Moderna participants. No difference in efficacy is reported between whites and people of color for either vaccine.

Myth: COVID-19 vaccines were developed using fetal tissue.

Fact: Neither the Pfizer/BioNTech COVID-19 nor the Moderna COVID-19 vaccines contain fetal cells nor were fetal cells used in the development or production of either vaccine.

Myth: COVID-19 vaccines cause infertility or miscarriage.

Fact: COVID-19 vaccines have not been linked to infertility or miscarriage by any scientifically plausible study.

Myth: I won't need to wear a mask after I get vaccinated for COVID-19.

Fact: Individuals who get the COVID-19 vaccination still need to practice infection prevention precautions until we get closer to herd immunity, when 75-80% of the population has been immunized or case counts have dropped to a minimal level. Vaccines do not stop the coronavirus from entering your body; they only prevent you from developing moderate to severe COVID-19. It is still possible that you could be an asymptomatic spreader even after being vaccinated. Until more is understood about how well the vaccine works, people should continue with precautions such as wearing a mask and practicing physical distancing.

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More Vaccine Q&A for Clinicians

The following is excerpted from the "COVID-19 Vaccine—Frequently Asked Questions" on the *New England Journal of Medicine* website, https://www.nejm.org/covid-vaccine/faq#Clinicians. This information is current as of January 29.

Should pregnant or breastfeeding women receive the vaccine?

Pregnant and breastfeeding women were not enrolled in the COVID-19 vaccine trials and as a result, data about safety is limited. Observational studies show that pregnancy is a risk factor for severe illness due to COVID-19, much as it is for influenza. Pregnant and lactating women should consider this information and their daily exposure to COVID-19 in making an informed decision.

Should patients who have recovered from COVID-19 receive the vaccine?

Yes. Some of the people who participated in the clinical trials had evidence of prior SARS-CoV-2 infection (based on a positive antibody test), and the vaccines were safe and effective in this group. However, patients who have been treated with monoclonal antibodies or convalescent plasma should wait 90 days before receiving the vaccine.

Does the second inoculation need to be the same vaccine?

Yes. Although the mechanism of action of the two vaccines is the same, they are not identical. The vaccines have not been studied this way, and such hybrid dosing strategies should be avoided.

Should acetaminophen or nonsteroidal anti-inflammatory drugs be taken *prior* to vaccination to prevent post-vaccination symptoms?

No. Although these drugs could decrease subjective side effects, theoretically they could also blunt immune response and make the vaccines less effective—hence they are not recommended before vaccination. However, they may be taken ***after*** vaccination to diminish side effects once they occur. Acetaminophen is preferred for pregnant women.

Continued

What capabilities need to be immediately available when the vaccine is administered?

The key capability is to have resources available to manage anaphylaxis. This includes both human resources such as nurses or pharmacists or doctors, along with equipment and supplies such as epinephrine, H1 antihistamines, blood pressure cuffs and stethoscopes. If feasible, offices should have pulse oxymeters, oxygen, IV fluids, and intubation kits.

Can the second dose be given sooner than 21 or 28 days if that will help to ensure it is received?

Vaccine sites should not routinely offer the second dose of the vaccine earlier than the recommended time interval between shots. However, if a person arrives early for the second dose of vaccine, the day of arrival is within the four-day grace period, and the person cannot return on the designated day (day 21 for Pfizer/BioNTech, day 28 for Moderna), then the vaccine should be given to ensure that the two doses are received.

Can the second dose be given later than 21 or 28 days and still be effective?

The CDC's latest guidance on January 21 says that when the recommended schedule is not feasible, the second dose may be scheduled for administration up to six weeks (42 days) after the first dose. Although data is currently limited on the efficacy of mRNA COVID-19 vaccines administered beyond this window, if the second is given later than this, the series still does not need to be restarted.

ALLIANCE

Dr. Sam Page Gives Update to Alliance Virtual Holiday Gathering

St. Louis County Executive and SLMMS member Sam Page, MD, addressed the virtual holiday gathering of the SLMMS Alliance on December 4. He provided an update on the fight against COVID-19. Members thanked him for his work and expressed strong support for public health efforts to contain the virus. Alliance donations were presented to the women's shelter St. Martha's Hall and the St. Louis Area Foodbank.

OBITUARIES

Arnold M. Goldman, MD

Arnold M. Goldman, MD, a board-certified internist, died November 26, 2020, at the age of 86.

Born in St. Louis, he earned his undergraduate degree from Harvard University, then graduated from Washington University School of Medicine. He completed his medical training at Johns Hopkins University School of Medicine and Barnes-Jewish Hospital. Dr. Goldman was an Army physician from 1966-68 and served in Vietnam during the Tet Offensive. He practiced internal medicine in St. Louis for more than 40 years.

Dr. Goldman joined the St. Louis Metropolitan Medical Society in 1963.

SLMMS extends its condolences to his wife Marilyn Goldman; his children Daniel Goldman, Sibyl Goldman, Edward Alport, David Alport and Richard Alport; and his four grandchildren.

David W. Robinson, MD

David W. Robinson, MD, an occupational medicine specialist, died December 23, 2020, at the age of 66.

Born in Kalvia, Finland, he obtained his medical degree from the American University of the Caribbean in the British West Indies. He completed his internship and an internal medicine residency at the former Deaconess Hospital. A member of the American College of Occupational and Environmental Medicine, Dr. Robinson served many companies and employees in the St. Louis area for 34 years.

Dr. Robinson joined the St. Louis Metropolitan Medical Society in 2000.

SLMMS extends its condolences to his wife Donna Robinson, and his children Steven Robinson and Andrew Robinson.

PARTING SHOTS

Beware of the Federal Government and the Office of Inspector General

By Richard J. Gimpelson, MD

I want to thank Denise Bloch, JD, for the very informative and revealing article that she authored in the December-January issue of *St. Louis Metropolitan Medicine*, "Beware of Pharmaceutical and Medical Device Speaker Programs." Attorney Bloch gave a plethora of information on how the feds and the Office of Inspector General (OIG) are watching and punishing physicians and companies for what they consider not just inappropriate, but illegal.

Over the years, I have been involved in at least 40 Food and Drug Administration Phase 2 and 3 medical device trials, gave hundreds of lectures, and proctored physicians throughout the United States as well as a number of international venues. I also ran many intensive hands-on training programs in minimally invasive gynecology at SSM Health DePaul Hospital. Every time I or any other physician participates in the above-mentioned programs, time is taken away from one's practice, yet there are bills to be paid, salaries to be paid and no practice income during the time away. Attorney Bloch revealed a number of red flag areas that physicians should avoid or risk fines up to $100,000, imprisonment up to 10 years or both. However in my opinion, we should receive a fair payment for our services we provide to the companies we are representing and to the colleagues we teach.

The feds' and OIG's rules can be twisted in order to punish physicians and companies. If a physician is highly skilled at using several products from different companies because one is optimal for different patient situations, it makes sense to use that product. It is also appropriate for the company to pay that physician for lecturing on and teaching the proper way to use that device. If a physician gives advice to a company regarding a new product development or improvement, that physician deserves to be paid appropriately as a consultant.

Three of my patents were licensed to companies, and I deserved the royalties that I was paid. In addition, because of my knowledge, lecture and teaching skills, it made sense for these companies to pay me for helping them teach other physicians how to use the device properly and safely.

If a physician like myself has participated in the FDA trials of devices and used the devices after they were cleared by the FDA for marketing, it only makes sense for that physician to be appropriately remunerated for working with that company to train other physicians. I wonder why the feds and OIG get to decide what a physician's time is worth when most occupations can charge what the market will pay.

I have advice for physicians that are hesitant to do work for medical device companies because of possible legal action by the feds or OIG: Get yourself hired as a consultant by an oil company in Ukraine or as an investment consultant by a bank in the People's Republic of China. It appears that neither of these jobs require prior experience but pay extremely well. Just make sure you declare the income to the IRS and pay the appropriate taxes. It is also OK to share the money with your parents.

Dr. Richard J. Gimpelson

Richard J. Gimpelson, MD, is a retired gynecological surgeon and past SLMMS president. The opinions expressed in this article do not necessarily represent the opinion of the Medical Society. Send comments on this column to editor@slmms.org.

CDC V-SAFE APP HELPS WITH VACCINE TRACKING

The Centers for Disease Control and Prevention have launched the **V-Safe** smartphone app as a follow-up tool for people who have received the COVID-19 vaccine. V-safe uses text messaging and web surveys to provide personalized health check-ins; it also provides a way for vaccine recipients to notify the CDC of any side effects. V-safe will also remind patients to get their second COVID-19 vaccine dose if needed. To enroll in V-Safe, the patient will need the vaccine card received after the first dose. For more information, https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html

Thank you for your investment in advocacy, education, networking and community service for medicine.

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Dr. Fauci Addresses WU Audience

Screenshot from Zoom conference.

The nation's leading infectious disease expert, Anthony S. Fauci, MD, sounded an optimistic tone for progress in the coming months against COVID-19, in remarks to a grand rounds presentation to faculty, students and residents at Washington University School of Medicine on January 7. Some highlights of his presentation:

- Our challenge now is to vaccinate as many people as possible.
- Mitigation measures such as mask wearing should continue until case counts drop to low levels and we have reached herd immunity.
- It's truly amazing that vaccines with 95% efficacy have been developed in less than 11 months. This is a great success.
- He encouraged students to pursue public health careers.
- Investment in public health should be restored to the level it was during the fight against tuberculosis.

Help is on the Way … ➨ *continued from page 11*

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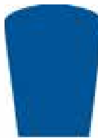

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