Senate Committee on Commerce February 25, 2021 Sarah Irsik-Good, MHA



Chair Olson, Vice Chair Steffen, and Members of the Committee, thank you for the opportunity to share information with you on behalf of KFMC Health Improvement Partners. My testimony **is submitted in opposition of Senate Bill 213**. KFMC is a not-for-profit consulting organization that works across Kansas, under contract with KDHE, with CMS, and many other private organizations to improve the healthcare delivered to Kansas residents. We have a long history of working to improve vaccination rates across Kansas and we believe this area of health improvement in fundamental to our vision of improved health outcomes for everyone. I am also a board member for the Immunize Kansas Coalition and serve as the Improved System Performance Team Chair. Currently, KFMC is working under the direction of CMS to improve vaccination rates for COVID-19, Influenza and Pneumonia in Kansas long-term care facilities, for both residents and staff, and it is in that capacity that I am speaking to you today.

While I suspect the primary motivation behind this bill is to prevent organizations from mandating the COVID vaccine for employees, it would have far reaching affects in other areas and other vaccine-preventable illnesses. This bill, if passed, would take us backwards by 10 years in the area of healthcare infection prevention. In April 2009, a Novel H1N1 influenza A strain of swine origin was identified. Unlike previous seasonal flu viruses, this pandemic virus disproportionately infected a wider age-range of people. In response to the H1N1 pandemic, many healthcare organizations moved toward mandatory vaccination policies and today many healthcare workers are required to receive certain vaccinations as a condition of their employment. The Equal Employment Opportunity Commission (EEOC), Occupational Health Safety Administration (OSHA) and the ADA have addressed the issue of mandatory flu vaccination policies in the past and determined that they are permissible. As such, this bill would undo the successes that have been achieved by these existing policies, and any future impact that mandatory vaccination policies could have on the current pandemic.

In my written testimony, I've linked a study showing the results of two randomized controlled studies evaluating the effect of healthcare worker vaccination on long term care residents. The study found that healthcare worker influenza vaccination was associated with a 44% decrease in resident mortality due to influenzaⁱ. The study also extrapolates that if 100% of those healthcare workers were vaccinated, that decrease in mortality would be as high as 60%. Now imagine if that reduction in mortality, or death, were translated to COVID 19 and LTC residents. Additionally, higher health care worker immunization rates help maintain a sustainable and effective health care workforce. Healthcare organizations' ability to make policies requiring vaccination as a condition of employment should be protected.

Vice Chair Steffen, I recently read an interview that you provided regarding your motivation behind supporting this piece of legislation, which you cited as individual rights. I would assume that most who support this piece of legislation do so out of a similar desire to protect individual choice. However, laws, policies and regulations that restrict individual liberties are frequently needed to ensure community health and safety. Communities routinely and justifiably make laws to create a safe place to live, like traffic laws, sanitation policies, occupational health and safety laws, and environmental regulations. Health care organizations and businesses should be allowed equal opportunity to protect those they serve, and those who live in, or pass through, their facilities.

In preparing my testimony today, I came across an articleⁱⁱ that used Garrett Hardin's classic essay *The Tragedy of the Commons* to demonstrate the challenges when society's interests conflict with the individual's interests. Hardin describes the incentives that are present when the cattle of a single community are comingled in a common pasture. At capacity, each cattle owner still has an incentive to add additional cattle to the common because even though the yield from each animal decreases with the addition of more cattle, that decrease is offset for the individual owner by the additional animal. With this incentive, individual owners continue to add cattle to the commons to reap their individual

benefit, leading to the inevitable failure of the common from overgrazing. The community interest in maximizing food production, therefore, can be achieved only by placing controls on the interests of the individual owners in favor of those of the community. A community protected from an infectious disease because of a high vaccination rate can be viewed as a common. As in Hardin's common, the very existence of this common leads to tension between the best interests of the individual and those of the community...and in the context of our discussion today, the interest of healthcare facilities, and other private businesses, to implement employee vaccination requirements, as they see necessary, to protect their employees, customers, patients and residents from vaccine-preventable disease. If we don't allow employers to establish requirements, many Kansans at high-risk for severe complications from vaccine-preventable disease, including infants, elderly, and immunocompromised individuals, may not be able to safely receive or access essential services.

However, I would argue that allowing businesses to make decisions about mandatory or compulsory vaccinations for their employees is not infringing on individual rights. Most mandatory vaccination policies still provide for limited exemptions and in many cases, some accommodations for those who decline. 12 years ago, I worked for a hospital that was implementing a mandatory vaccination policy for the flu vaccine. Those who declined were required to wear a mask when providing patient care during flu season. Seeing someone wear a mask all the time was a lot more of an anomaly then, but it was an accommodation none-the-less. Additionally, Kansas is still an at-will employment state; employees who oppose vaccinations are free to elect to work for employers whose policies meet their individual needs and expectations, just like we, as a society, do every day regarding salary, benefit packages, work schedules, etc. Everyone should be able to make life decisions, including employment decisions, based on what they believe and what is in the best interest of their customers, family, friends, etc.

Many of my talking points have revolved around influenza, so why not just ask you to amend the bill to leave most mandatory vaccination policies alone, and carve out the COVID Vaccine for protection? The coronavirus pandemic has placed a large burden on hospitals and healthcare providers, which increases the risk of healthcare-associated transmission and outbreaks to "non-COVID" patients or residents, who represent the highest-risk population in terms of mortalityⁱⁱⁱ. To date, there are several reports of healthcare associated outbreaks of COVID and although the attack rate, or percentage of patients who contract the disease, is variable, we do know that it was as high as 100% in least one facility right here in Kansas. I know that this bill was written, at least partially, in response to fear and uncertainty around the COVID vaccines and misconceptions about vaccine safety. I won't go into that today, although I have included a COVID Vaccine fact sheet developed by KFMC if you're curious about what some of those hesitations are and the facts about these specific vaccines. In the end, rumors and fear must not be a barrier to promoting patient safety and public health; it should also not be the reason we undo policies that have been in place and saving lives for more than a decade. As such, we **oppose SB 213**. Thank you!

Sarah A. Irsik-Good, MHA President & CEO KFMC Health Improvement Partners

ⁱ Abigale L. Ottenberg, MA, Joel T. Wu, JD, MA, MPH, Gregory A. Poland, MD, Robert M. Jacobson, MD, Barbara A. Koenig, PhD, and Jon C. Tilburt, MD, MPH. "Vaccinating Health Care Workers Against Influenza: The Ethical and Legal Rationale for a Mandate. <u>Am</u> J Public Health. 2011 February; 101(2): 212–216.doi: <u>10.2105/AJPH.2009.190751</u>

ⁱⁱ Malone, Kevin M. and Hinman, Alan R. "Vaccination Mandates: The Public Health Imperative and Individual Rights". <u>Control and Prevention</u>. Accessed at <u>Chapter 13 - Vaccination Mandates: The Public Health Imperative and Individual Rights - (cdc.gov)</u> on February 23, 2021.

^{III} Abbas, M., Robalo Nunes, T., Martischang, R. *et al.* Nosocomial transmission and outbreaks of coronavirus disease 2019: the need to protect both patients and healthcare workers. *Antimicrob Resist Infect Control* **10**, 7 (2021). <u>https://doi.org/10.1186/s13756-020-00875-7</u>. <u>https://aricjournal.biomedcentral.com/articles/10.1186/s13756-020-00875-7#citeas</u>

COVID-19 Vaccine FACT SHEET

Pfizer (mRNA Vaccine) 95% effective* 2 dose series (0.3mL each) given 21 days apart Multidose vial containing up to 6 doses/vial Dilute with 1.8 mL of 0.9% Sodium Chloride 43,448 trial participants Authorized for use in individuals > 16 years Published safety and final efficacy results from Phase 3 trial on December 10, 2020

Moderna (mRNA Vaccine) 94.5% effective* 2 dose series (0.5 mL each) given 28 days apart Multidose vial containing 10 doses No dilution required 30,420 trial participants

Authorized for use in individuals > 18 years

Announced primary efficacy results from Phase 3 trial on November 30, 2020

*vaccine efficacy is against COVID-19 in individuals without prior SARS-CoV-2 infection

What is mRNA and how do mRNA vaccines work?

- Messenger RNA, or mRNA, is the blueprint for making proteins. Within the nucleus of cells, DNA makes mRNA and then ships it into the surrounding cell cytoplasm. In the cytoplasm, mRNA is translated into proteins and enzymes. Soon after this, the mRNA breaks down.
- COVID-19 mRNA vaccines take advantage of the cellular process of making proteins by introducing mRNA that contains the blueprint for one of the coronavirus proteins, specifically the spike protein. This protein is responsible for attaching the coronavirus to our cells.
- COVID-19 mRNA vaccines are given in the upper arm muscle. Once the mRNA is inside the immune cells of the muscle tissue, the cells follow the instructions and make the spike protein piece.
- Next, the cell displays the protein piece on its surface. Our immune system recognizes that the protein • doesn't belong there and begins mounting an immune response and making antibodies.
- After developing antibodies, our immune system can protect against future infection.
- The benefit of the mRNA vaccine is those vaccinated gain the protection without risking the serious consequences of getting sick with COVID-19.

Are mRNA vaccines safe?

Most commonly reported side effects, which are a consequence of the body's immune response to the SARS-CoV-2 spike protein, include:

Injection Site Reaction	Fatigue	Muscle Pain	Joint Pain
Low-grade Fever	Headache	Chills	

Side effects are most common after the second dose and in people younger than 55. Typically, these side effects last only 1-2 days.



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COVID-19 Vaccine FACT SHEET

What other ingredients are included in the vaccines?

There has been complete transparency around ingredients. You can find the fact sheet for each vaccine posted on the FDA's website with the exact list of ingredients. In addition to the mRNA, both vaccines include:

- *Lipids:* Molecules or "bubbles of fat" that surround the mRNA to protect it, so it does not break down before it gets into our cells.
- *Salt:* Similar to table salt, it keeps the pH of the vaccine close to that of the body, so the vaccine doesn't damage the cells.
- *Sugar:* Similar to sugar we eat, in the vaccine it helps keep the "bubbles of fat" from sticking to the vaccine vial.

Fact or Fiction?

- Fact: COVID-19 mRNA vaccines cannot give someone COVID-19. mRNA vaccines do not use the live virus that causes COVID-19.
- Fact: COVID-19 mRNA vaccines do not affect or interact with our DNA in any way. mRNA never enters the nucleus of the cell, which is where our DNA (genetic material) is kept. The cell breaks down and gets rid of the mRNA soon after it finishes following the instructions.
- Fact: There is no aluminum, mercury or food allergens in the ingredients list. This is great news for those who may have allergy concerns or be vaccine hesitant.
- Fact: The short-term, easily managed side effects are significantly less risky than taking your chances with the COVID-19 infection.
- Fact: COVID-19 infection has a 99% survival rate. Surviving and Thriving are incredibly different. COVID-19 symptoms can persist for months. The virus can damage the lungs, heart, and brain which increases the risk of long-term health problems. Even young, otherwise healthy people can feel unwell for weeks to months after the infection.
- Fiction: mRNA Vaccine Technology is new and untested. *mRNA technology was discovered over 30 years ago* and has been studied for vaccine purposes for nearly two decades. Scientists have been working on a coronavirus vaccine since the SARS and MERS outbreaks, but once the pandemic ended and the virus was no longer circulating, the funding dried up. No funding = no scientific advancements. Early-stage clinical trials using mRNA vaccines have been carried out for influenza, Zika, rabies, and cytomegalovirus (CMV). Recent technological advancements in RNA biology and chemistry, as well as delivery systems, have mitigated these challenges and improved their stability, safety and effectiveness.
- Fiction: mRNA Vaccines cause infertility in women of child-bearing age, since the spike protein the body creates after vaccination is like a protein in the placenta of pregnant mothers. The FDA says there is no reason to believe the vaccine causes infertility. Doctors say the two are not similar enough for the spike protein to launch an immune response to the placenta that would endanger the mother's ability to carry a baby to term.

Short-term side effects and up to 95% vaccine efficacy > long-term health consequences of COVID-19 infection. Get vaccinated at your first opportunity!



Thank you to Tiffany A. Dickey, PharmD, BCIDP, Medical Science Liaison Vaccines, US Medical Affairs, Sanofi Pasteur for her review and input on this fact sheet.

COVID-19 Vaccine FACT SHEET

Reference List:

"Q & A COVID-19 mRNA Vaccines: What you should know". Children's Hospital of Philadelphia Vaccine Education Center. Retrieved from <u>https://media.chop.edu/data/files/pdfs/vaccine-education-center-covid-qa.pdf</u> on 19 January 2021.

"Pfizer-BioNTech COVID-19 Vaccine". Centers for Disease Control and Prevention. Retrieved from on 14 January 2021 https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/index.html.

"Pfizer-BioNTech Covid-19 Vaccine". Labelling. Retrieved 19 January 2021 form on http://labeling.pfizer.com/ShowLabeling.aspx?id=14471.

"Moderna COVID-19 Vaccine". Centers for Disease Control and Prevention. Retrieved on 14 January 2021 from <u>https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/index.html</u>.

"Fact Sheet for Healthcare Providers Administering Vaccine (Vaccine Providers): Emergency Use Authorization (EUA) of the Moderna COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID 19). ModernaTX. Retrieved on 19 January 2021 from https://www.modernatx.com/covid19vaccine-eua/eua-fact-sheet-providers.pdf.

"Understanding and Explaining mRNA COVID-19 Vaccines". The Centers for Disease Control and Prevention. Retrieved on 12 January 2021 from https://www.cdc.gov/vaccines/covid-19/hcp/mrna-vaccine-basics.html.

"Understanding mRNA COVID-19 Vaccines". The Centers for Disease Control and Prevention. Retrieved on 12 January 2021 from https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/mrna.html.

"Vaccines and Related Biological Products Advisory Committee Meeting December 17, 2020: FDA Briefing Document Moderna COVID-19 Vaccine". Food and Drug Administration. Retrieved on 12 January 2021 from https://www.fda.gov/media/144434/download.

"Vaccines and Related Biological Products Advisory Committee Meeting December 10, 2020: FDA Briefing Document Pfizer-BioNTech COVID-19 Vaccine". Food and Drug Administration. Retrieved on 12 January 2021 from https://www.fda.gov/media/144245/download.

"Moderna Announces Primary Efficacy Analysis in Phase 3 COVE Study for Its COVID-19 Vaccine Candidate and Filing Today with U.S. FDA for Emergency Use Authorization". November 30, 2020. Retrieved from <a href="https://investors.modernatx.com/news-releases/news-release

"Pfizer and BioNTech announce Publication of Results from Landmark Phase 3 Trial of BNT162B2 COVID-19 Vaccine Candidate in the New England Journal of Medicine". December 10, 2020. Retrieved from https://www.pfizer.com/news/press-release/press-release/ detail/pfizer-and-biontech-announce-publication-results-landmark

"COVID-19 (coronavirus): Long Term Effects". The Mayo Clinic. Retrieved on January 12, 2021 from <u>https://www.mayoclinic.org/diseases-</u> conditions/coronavirus/in-depth/coronavirus-long-term-effects/art-20490351

"Fact Sheet for Recipients and Care Givers: Emergency Use Authorization (EUA) of the Pfizer-BioNTech COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19) in Individuals 16 years of Age and Older". The Food and Drug Administration. Retrieved on January 12, 2021 from https://www.fda.gov/media/144414/download

"Fact Sheet for Recipients and Care Givers: Emergency Use Authorization (EUA) of the Moderna COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19) in Individuals 18 years of Age and Older". The Food and Drug Administration. Retrieved on January 12, 2021 from https://www.fda.gov/media/144638/download

"Vaccines for SARS-CoV-2: Lessons from Other Coronavirus Strains". Infect Dis Ther. 2020 Jun; 9(2): 255-274. Published online 2020 Apr. 23. Doi:10.1007/s40121-020-00300-x

"Pfizer-BioNTech COVID-19 Vaccine Frequently Asked Questions". Food and Drug Administration. Retrieved on January 19, 2021 from https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/pfizer-biontech-covid-19-vaccine-frequently-asked-questions



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