

## House Committee on Education February 13, 2020

Chair Huebert, Vice Chair Dietrick and Members of the Committee, as the CEO of the Kansas Foundation for Medical Care (KFMC) I leverage over 20 years' experience in the healthcare industry in furthering KFMC's mission to improve the quality, safety and effectiveness of healthcare in Kansas. This mission is aligned with the mission of the Immunize Kansas Coalition (IKC), to protect Kansas from vaccine-preventable diseases. As such, KFMC is an institutional member of the coalition and I personally serve on the coalition's Board of Directors. My testimony, both written and in person, is submitted in **opposition of House Bill 2601**.

IKC is a group of Kansas providers, health department officials, researchers and educators working together to improve the health of Kansas through improved vaccination rates to protect against vaccine-preventable diseases. Both IKC and KFMC are independent and objective sources of evidence and facts, contrary to some of the misinformation you may have received (see #11, 12 and 13 in the attached assessment of facts). IKC's members volunteer their time and resources to support our mission of protecting every Kansan from vaccine preventable diseases. We do this work because we believe in the science behind the vaccine recommendations, and like you, we want only the best for the residents of Kansas. One of our goals is to provide education and information, which will empower you, as legislators, to process and respond to the information you are receiving in an informed way.

It is important that changes to the list of mandatory school vaccinations remain in the current regulation process and are not moved to the legislative process. All fifty states have statutes related to mandatory school vaccinations, and each of those states allow the state department of health to require other diseases on a long-term basis in order to respond to changes in the Advisory Committee on Immunization Practices (ACIP) recommendations. Allowing the state department of health to respond timely to the best scientific recommendations for immunizations as set forth by ACIP, and adjust the list of required vaccines, minimizes the potential risk to Kansas' school children.

The current regulation process allows a timely response to changes in ACIP recommendations, both to add *and* remove vaccines from the requirements list. If vaccines were listed in statute, the ability to respond to recommended changes in a timely manner would be hampered due to the limits of the legislative process for introducing and approving bills.

Since we also live and work in the Kansas community, we know that mandatory vaccination is a position that some groups passionately oppose. Those groups are also very active in creating messaging, sharing information, and telling stories to support their position. In addition to providing KFMC's support for maintaining the status quo, this communication is also intended to address some of the mis-information you have been receiving recently and to help you identify what is true and what is not. It is easy to get caught up in the emotion and the grief of



parents and children who are genuinely suffering. It is a common understanding that doctors who see disease support vaccination; activists who see grief support a loose idea of freedom.

Understanding what is true and what is false is sometimes difficult, unless you have hours to devote to research and fact-finding missions. Additionally, sometimes the sheer volume of information you are receiving is overwhelming. It is important, as lawmakers, for you to understand that misinformation relating to vaccines is widespread and it is this misinformation that has led to the decrease in public confidence and not a lack of evidence supporting the safety of vaccines.

## In a world full of chaos and mis-information, where do you go to find the truth?

As mentioned previously, both KFMC and IKC are an independent and objective source of information, without conflict, and without affiliation to or with a specific provider type or organization. Based on the information you may have received directly in emails and other media communications, it's important to identify what is true and founded in science, and what is not:

1. Childhood vaccinations cause Autism – FALSE

There is a preponderance of evidence to the contrary. The American Academy of Pediatrics has complied a list of evidence-based, peer-reviewed articles published in scientific journals studying the long-term effects of vaccines, including 27 independent research articles supporting the factual statement that vaccines **DO NOT** cause Autism.

 Vaccines cause autoimmunity and autism due to fetal DNA contaminants – MISINTERPRETATION of supporting references resulting in an UNSUPPORTED claim.

This assertion first appeared based on a Vaccine Impact article published May 19, 2019. There are several problems with this article and this claim, specifically that the article itself is a misrepresentation of cited references, which were not used appropriately and/or were taken out of context. Secondly, the claim that such DNA causes autoimmunity is unsupported by science. First, it is important to understand that Immunologists do acknowledge that certain vaccines are produced using human fetal-derived cell lines, but the study being referenced *does not demonstrate the actual presence of fetal DNA in vaccines in any capacity*. There are methodological issues with the study which call into question the findings. <sup>1</sup> Additionally, the reference list that was used to support the article's claim shows that the citations were not used appropriately,

<sup>&</sup>lt;sup>1</sup>Article claiming vaccines cause autoimmunity and autism due to fetal DNA contaminants found unsupported and implausible (June 2019), retrieved from <u>https://healthfeedback.org/evaluation/article-claiming-vaccines-cause-autoimmunity-and-autism-due-to-fetal-dna-contaminants-found-unsupported-and-implausible-theresa-deisher/</u>



were used out of context, or where misinterpreted.<sup>2</sup> Finally, Immunology experts also assert that it is implausible for "....recombination of fetal DNA after vaccination to cause autoimmunity and autism, since it necessitates a chain of events that are extremely unlikely to happen all together, especially in the biological context of a living person and not the artificial environment of a test tube." If that were plausible, pregnant women, who have higher levels of fetal DNA circulating constantly over 9 months, would have a higher incidence of cancer, and they do not.<sup>2</sup>

3. The cumulative number of vaccines in the immunization schedule have not be studied or examined together – **MISREPRESENTATION** of facts.

Use caution when evaluating evidence that is incomplete or taken out of context. The communications recently received with this assertion also include a YouTube link to a video of snippets pieced together from the Global Vaccine Summit (December 2019) asserting that even vaccine experts question their safety and lack of testing. This video was edited and put together by the producer of the movie *Vaxxed* and done so with an agenda. Please always consider the primary source of the information to fully understand the context in which comments are made. For example, the 2013 IOM Report that has been quoted regarding the safety of the vaccine schedule left out a key component of the report. The quote provided is from the report summary and the full quote states "no study has directly examined the health outcomes *and stakeholder concerns in precisely the way that the committee was charged to address in its statement of task.*"

The full report states quite the opposite of what is being represented in emails you have been receiving:

"The Food and Drug Administration's (FDA's) current protocol for approval of new vaccines requires an evaluation of the effect of administration of a new vaccine along with other vaccines within the preexisting schedule. Therefore, the burden of disease and evidence of adequate immunogenicity when vaccines are administered together with existing recommended vaccines are established at the time of FDA approval and development of a recommendation by the ACIP. Although the committee's review of the available scientific evidence revealed that no potential adverse health outcomes that may occur after immunization with the recommended immunization schedule rose to a level of concern or biological plausibility sufficient to justify a strong recommendation for

<sup>&</sup>lt;sup>2</sup> Article claiming vaccines cause autoimmunity and autism due to fetal DNA contaminants found unsupported and implausible (June 2019), retrieved from <u>https://healthfeedback.org/evaluation/article-claiming-vaccines-cause-autoimmunity-and-autism-due-to-fetal-dna-contaminants-found-unsupported-and-implausible-theresa-deisher/</u>



*immediate study,* the committee was asked to recommend methodological approaches that could be implemented should the need arise."<sup>3</sup>

4. Dr. James R. Shannon, director of the National Institute of Health (NIH) stated "The only safe vaccine is the one that is never given." - **TRUE** 

Dr. Shannon did indeed make this statement when he was the director of the NIH...*from* **1955 to 1968**<sup>4</sup>. Nine years of his tenure with the NIH was **PRIOR** to the introduction and testing of the Polio vaccine in 1964.

5. Vaccines never go through the double-blind placebo-controlled studies that are required of other drugs - FALSE

In such a trial the group of participants is randomly assigned into either a control group or an experimental group. This assignment is completely at random, and the people going into either group are not aware of what group they're in. The researchers also do not know what group the participants are. The intention behind this is to obtain experimental and control groups that are like each other in every way, such as age, gender or ethnicity. The argument for blinding the participants and the researchers seeks to eliminate bias because the participants are not aware if they are receiving the real deal (thus making them less likely to underreport or overreport outcomes) and the researchers also don't know (thus making them less likely to more closely observe one group over the other). At the end of the study, the number of outcomes are counted in each group and the resulting rates compared. An example of this type of trial that in the history of vaccines is the trial of the polio vaccine in 1954 and the clinical trials used in the development and testing the measles vaccine.

In evaluating this statement, it's important to understand when a randomized clinical trial is warranted. In the case of the polio vaccine, it was necessary to know if the vaccine was better than what was available at the time to prevent polio, which was nothing at all. If there is already a known vaccine that is safe and effective, it may be unethical to randomize children into an unvaccinated group because such a process would be denying them the benefits of being vaccinated. Further, parents who oppose vaccination would likely not allow their children to be randomized into a vaccinated group, and parents who are not likely to see a physician may not bring a child with an infection to a physician, further biasing the results of a study.

<sup>&</sup>lt;sup>3</sup> Committee on the Assessment of Studies of Health Outcomes Related to the Recommended Childhood Immunization Schedule; Board on Population Health and Public Health Practice; Institute of Medicine. The Childhood Immunization Schedule and Safety: Stakeholder Concerns, Scientific Evidence, and Future Studies. Washington (DC): National Academies Press (US); 2013 Mar 27. 6, Methodological Approaches to Studying Health Outcomes Associated with the Current Immunization Schedule: Options, Feasibility, Ethical Issues, and Priorities. Available from: https://www.ncbi.nlm.nih.gov/books/NBK206942/ <sup>4</sup> https://www.nih.gov/about-nih/what-we-do/nih-almanac/james-shannon-md



6. The US Supreme Court has ruled that vaccines are "unavoidable safe" – FALSE

This is a false representation of Bruesewitz v. Wyeth, 562 U.S. 223 (2011). The Supreme Court has never held or decided, or affirmatively stated as a proposition of medical fact that vaccines are "unavoidably unsafe". The issue in this case was whether a vaccineinjured party could pursue a design-defect lawsuit under state law after an adverse decision from the federal vaccine court. The rule of law that was used in support of the Supreme Court decision held that state vaccine injury lawsuits are preempted by federal law. It is in the dicta, the additional discussions which the majority and dissent opinion writers put into their respective opinions, that has led to the incorrect notion that the Supreme Court stated that vaccines are "unavoidably unsafe". The opinions reference a committee report from 1986, which adopted comments from §402A of the Restatement of Torts (Second)(1963-1964) which provides that "unavoidably unsafe" products (i.e. those that "in the present state of human knowledge are quite incapable of being made safe for their intended and ordinary use") are not defective. An example of an "unavoidably unsafe" product referenced in this statute is "the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when injected"; "[s]ince the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve."<sup>5</sup>

7. Who in Kansas is responsible for vaccine injury to Kansas residents?

One option for Kansas residents is the National Vaccine Injury Compensation Program (VICP)<sup>6</sup>. Most people who get vaccines have no serious problems. Vaccines, like any medicine, can cause side effects, but most are very rare and very mild. Some health problems that follow vaccinations are not caused by vaccines.

In very rare cases, a vaccine can cause a serious problem, such as a severe allergic reaction. In these instances, VICP may provide financial compensation to individuals who file a petition and are found to have been injured by a VICP-covered vaccine. Even in cases in which such a finding is not made, petitioners may receive compensation through a settlement.

<sup>&</sup>lt;sup>5</sup> 562 U.S. 223 (2011). Retrieved from <u>https://www.law.cornell.edu/supct/html/09-152.ZD.html</u>.

<sup>&</sup>lt;sup>6</sup> National Vaccine Injury Compensation Program (VICP), <u>https://www.hrsa.gov/vaccine-compensation/index.html</u>



8. Parents are told that seizures, fevers and excessive sleepiness were "normal" following their child's vaccines – FALSE

According to the CDC's Parent Guide for vaccinations, babies often get a sore leg/limb or a mild fever after vaccinations, but more serious reactions are uncommon, and parents should contact their provider know. While this is but one example, most patient information is based on the same science and would include messaging consistent with the CDC messaging.<sup>7</sup>

9. It's not the government's job to make medical decisions for me and my family - FALSE

"The Court held that a health regulation requiring smallpox vaccination was a reasonable exercise of the state's police power that did not violate the liberty rights of individuals under the Fourteenth Amendment to the U.S. Constitution. The police power is the authority reserved to the states by the Constitution and embraces "such reasonable regulations established directly by legislative enactment as will protect the public health and the public safety" (197 U.S. at 25, 25 S.Ct. at 361)."<sup>8</sup> We see this protection of public health and public safety and the same exercise of the government's obligation through the mandatory quarantine of Coronavirus patients.

10. Line 13.1 of every single vaccine insert states: "...has not been evaluated for carcinogenic or mutagenic potential, or for impairment of fertility" – **PARTIALLY TRUE** 

The Code of Federal Regulations require that non-clinical toxicology be outlined in the vaccine insert:

"13.1 Carcinogenesis, mutagenesis, impairment of fertility. This subsection must state whether long term studies in animals have been performed to evaluate carcinogenic potential and, if so, the species and results. If results from reproduction studies or other data in animals raise concern about mutagenesis or impairment of fertility in either males or females, this must be described. Any precautionary statement on these topics must include practical, relevant advice to the prescriber on the significance of these animal findings. Human data suggesting that the drug may be carcinogenic or mutagenic, or suggesting that it impairs fertility, as described in the "Warnings and Precautions" section, must not be included in this subsection of the labeling."<sup>9</sup>

<sup>&</sup>lt;sup>7</sup> Parent's Guide to Childhood Immunizations (August 2015), <u>https://www.cdc.gov/vaccines/parents/tools/parents-guide/downloads/parents-guide-508.pdf</u>

<sup>&</sup>lt;sup>8</sup> Malone, K.M. & Hinman, A.R., *Vaccination Mandates: The Public Health Imperative and Individual Rights, (2003)* <u>https://www.cdc.gov/vaccines/imz-managers/guides-pubs/downloads/vacc\_mandates\_chptr13.pdf</u>

<sup>&</sup>lt;sup>9</sup> CFR – Code of Federal Regulations Title 21



New vaccines undergo preclinical toxicology studies which are conducted prior to the initiation of, and concurrently with, clinical studies. If the package insert says that it has "not been evaluated", it is simply because it was not necessary or appropriate, not that they just didn't want to do it or left those tests out. All necessary pre-clinical or nonclinical testing is done on vaccines and their components. You just don't see long term testing that would be listed in the package insert unless the initial tests found a problem. Finally, vaccines are also monitored through several passive and active safety systems that would detect issues with mutagenicity carcinogenicity, and impairment of fertility. <sup>10</sup>

11. The Vaccine Adverse Event Reporting System (VAERS) receives an average of 30,000 reports per year. However, a Harvard study found that fewer than 1% of vaccine adverse events are reported – **SOMEWHAT TRUE** 

The Harvard Study<sup>11</sup> states that fewer than 1% of vaccine events are reported to the Food and Drug Administration (FDA) for identification of "problem" drugs and vaccines that endanger public health. The data reviewed for this report was from June 2006 through October 2009. This statement is no longer accurate as the Vaccine Adverse Event Reporting System (VAERS) now provides reported data to both the CDC and the FDA concurrently.<sup>12</sup>

12. The Immunize Kansas Coalition (IKC) is affiliated with all the major vaccine manufacturers – FALSE

The graphic provided to legislators is a list of the affiliated members; the list is of those members affiliated with IKC. IKC is a 501(c)3 organization with established bylaws defining membership and voting rights. Membership categories include three levels:

- a. <u>Institutional Membership</u>: open to all institutions, organizations, and agencies who support and agree to work toward the mission of the coalition; designate one representative to serve as the voting member
- b. <u>Individual Membership</u>: open to any individual, professional, student, honorary, or retired coalition members not otherwise included as an institution member; considered a voting member

<sup>&</sup>lt;sup>10</sup> Vaccine. 2017 Oct 13;35(43):5762-5767. doi: 10.1016/j.vaccine.2017.09.021. Epub 2017 Sep 12.

<sup>&</sup>lt;sup>11</sup> Grant ID: R18 HS 017045, Grant Final Report. Electronic Support for Public Health – Vaccine Adverse Event Reporting System (ESP:VAERS), Accessed at

https://digital.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf <sup>12</sup> Vaccine Adverse Event Reporting System Brochure, Published by HHS, FDA, and CDC.

https://www.fda.gov/files/vaccines,%20blood%20&%20biologics/published/Vaccine-Adverse-Event-Reporting-System-Brochure.pdf



c. <u>Liaison Members</u>: open to pharmaceutical companies, because of the potential for receiving financial gain from the mission, they are eligible for liaison membership only; non-voting members and liaison members are not eligible to serve on the board of directors.

IKC is not affiliated with vaccine manufacturers, nor are it's institutional and individual members. Participation by representatives of vaccine manufacturers is intentionally limited to avoid even the appearance of undue influence or conflict. However, they do provide many, unbranded resources to the provider and patient communities at no cost.

The assertion also states: "To what extent is money from these liability-free pharmaceutical companies--companies that have all been convicted of fraud for lying about the safety of their products--influencing the KDHE's vaccine recommendations?" First, IKC and KDHE are separate organizations. Second, *neither IKC or KDHE have received any money from any pharmaceutical companies who do or do not participate in coalition activities*. IKC has an established funding support policy in place to prevent such a conflict. This policy states: "These guidelines were designed to ensure that funds are used to support activities that are consistent with the mission and scope of IKC and to minimize potential conflicts of interest and the appearance of conflicts of interest. They are consistent with policies of other nonprofit, public health membership associations."

13. One of the main goals of IKC is to raise vaccination rates for the HPV vaccine to 80% by 2026 – TRUE

IKC established the current goals as a full coalition, with the 80% HPV vaccine goal being adopted to align with the American Cancer Society's goal and the Healthy People 2020 goal, a science-based, 10-year national objective for improving the health of all Americans. Work toward this goal is how we begin working toward herd immunity. The HPV vaccination has been recommended since 2011 by the Advisory Committee on Immunization Practices (ACIP) for both boys and girls. The HPV vaccine reduces the risk for HPV-related cancers. In the United States, each year HPV causes about 17,600 cancers in women and 9,300 cancers in Men. Kansas ranks among the lowest states when comparing HPV vaccination rates for adolescents nationally, prompting IKC to focus its attention on this life-saving cancer vaccine. Nearly 80 million Americans are currently infected with some type of HPV with the potential for 14 million new infections each year, making it a priority public health issue. Finally, it is important to note that IKC's mission is to protect all Kansans from vaccine preventable diseases and while mandatory school vaccination and exclusion policies are a component of the work IKC does, it is just one of many priorities impacting other populations.



14. FDA Announced that 73.3% of girls in HPV (Gardasil) developed new illnesses – **Presented as a MISCHARACTERIZATION of data** 

This is a **misrepresentation** of the data. The FDA report did state that 73.3% of the subjects in the Gardasil group reported new medical history. The report also stated that 76.3% of subjects in the Placebo group also reported new medical history, more than the Gardasil group<sup>13</sup>.

Thank you for the opportunity to present our concern and opposition of this legislation, and to provide you with the necessary information that supports informed decision making with regard to HB 2061.

Sarah Irsik-Good, MHA CEO, Kansas Foundation for Medical Care Immunize Kansas Coalition Board of Directors

<sup>&</sup>lt;sup>13</sup> Clinical Review of Biologics License Application Supplement for Human Papillomavirus Quadrivalent (Types 6, 11, 16, 18) Vaccine, Recombinant (Gardasil<sup>®</sup>) to extend indication for prevention of vaginal and vulvar cancers related to HPV types 16 and 18, page 137. Retrieved from <u>https://www.fda.gov/media/74361/download</u>