MOBIO
MISSOURI BIOTECHNOLOGY ASSOCIATION

March 22, 2023

The Honorable Bill Hardwick, Chairman
House Committee on Emerging Issues
Missouri House of Representatives
Jefferson City, MO 65101

Dear Chairman Hardwick,

The Missouri Biotechnology Association respectfully expresses our serious opposition to HB 1169. Our concerns include the following:

- HB 1169 is unnecessary, as federal law and jurisdiction are already in place.
- HB 1169 comingles and convolutes established scientific processes that already have investigational, clinical, and regulatory meanings, which will set Missouri statutes at odds with other states, the federal government, and foreign trade partners.
- HB 1169 will have a chilling effect on how we market Missouri as a welcoming biosciences ecosystem.
- HB 1169 enables provisions that will open the floodgates on proprietary disclosures, harming researchers, biotech start-up entrepreneurs, and Missouri bioscience employers.

Initiating a state labeling mandate that leverages vaccine hesitancy while needlessly stoking the public's food fears and scaring consumers is irresponsible.

Our US Congress passed federal legislation in 2016, originally sponsored by Congressman Mike Pompeo of Kansas, to avert what it feared would be a patchwork of inconsistent state-by-state regulations across our country. This national interstate commerce standard under the United States Department of Agriculture (USDA) also bans and preempts individual state labeling laws on food products. That seven-year-old law of the land already directs food manufacturers on the different regulatory pathways - including organic, natural, and genetically engineered.

All citizens desire that products in our food supply chain are regulated appropriately for safety and efficacy claims that can be scientifically evaluated and/or validated. The USDA and the Food and Drug Administration (FDA) are the world's gold evaluation standards. Collectively, we should be united on strengthening the scientific depth and expertise at these important agencies.

In 2019, the United States Department of Agriculture announced it was moving two of its key agencies' headquarters to Missouri. USDA's Economic Research Service and the National Institute of Food and Agriculture's headquarters are located at 805 Pennsylvania Avenue in Kansas City, Missouri. More than 500 new jobs shifted from the nation's capital to the heartland. HB 1169 could be seen as an affront to that decision to relocate to our state. At a minimum, it will be seen as a lack of understanding by Missouri of the USDA's appropriate role and importance.

In terms of economic development, House Bill 1169 would be a major disqualifier for any plant science company looking to locate in Missouri. Site locators must be able to recommend that Missouri has the right business environment, with the appropriate respect and understanding for plant science researchers.

Lumping together overly broad definitions for the terms "gene therapy product" and "genetically modified" is an overreach that will negatively impact many constituencies.

For example, Missouri's corn and soybean row crop farmers utilize genetically modified seed in over 90% of their plantings. Farmers make seed decisions and purchases around the first of each calendar year. An unintended consequence of having this or any Missouri harvest segregated from export markets could hurt Missouri farmers, which is the critical driver for much of Missouri's rural economy, an agricultural industry valued at $94 billion for Missouri. The agtech workforce consists of more than 460,000 Missourians, as presented by the Missouri Partnership.

Missouri policymakers should be embracing the scientific and medical advancements behind gene therapy products and Missouri's role in contributing to this scientific knowledge base. In addition, Missouri policymakers should be aware that biosciences have been one of the state's top economic and strategic sectors for the last two decades, delivering that new economic growth to our state.

MOBIO provides additional information for your situational analysis. We hope it is helpful.

Thank you for allowing us to share the policy ramifications of HB 1169.

Respectfully submitted,

Kelly Gillespie
Executive Director

Gene Therapy Background information

According to the FDA, gene therapy is the administration of genetic material "to modify or manipulate the expression of a gene product or to alter the biological properties of living cells for therapeutic use."

At the end of 2022, the FDA approved 27 products. This first round of gene therapy products has enabled us to reprogram a patient's own cells to attack deadly conditions like advanced-stage cancer, blindness, and spinal muscular atrophy. In addition, gene therapy products aim at curing, and often their patient populations target rare diseases or inherited disorders.

Gene therapy products in the pipeline are robust: the FDA expects 200 investigational new drug applications per year, by 2025, it expects to approve between 10 and 20 gene therapy products per year. However, gene therapy products are expensive, with public reports revealing costs of several hundred thousand dollars to over $2 million per dose. Gene therapy clinical success also faces a constant hurdle in targeting specific tissues without triggering an immune response.

mRNA Background information

The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) pandemic, as of August 26, 2022, has led to over 599 million cases of COVID-19, including 6.4 million deaths worldwide. Additionally, John Hopkins Coronavirus Resource Center reports Missouri had 1.7 million confirmed cases and 22,870 deaths to (or with) Covid.

mRNA biology is referred to as the blueprint for all protein synthesis, using cell biology to activate immune systems. mRNA has inherent safety features as it does not self-replicate, mRNA does not enter the nucleus or integrate into the patient's DNA, and the manufacturing process is cell-free and contains no human or animal products.

This time, three years ago, President Trump had not even announced Operation Warp Speed. In the US, six to seven different technologies were pursued non-replicating viral vectors, adenovirus viral vector, spike protein nanoparticles, immune response therapies, protein cell lines, and of course, mRNA technologies, which ended up getting significant attention.

Messenger RNA, or Messenger Ribonucleic acid, or mRNA, is a type of single-stranded RNA involved in protein synthesis. The mRNA companies detailed in their applications that the mRNA remains in the cytoplasm (a cell's watery interior) until eliminated by natural mRNA decay; to alter the DNA, it would need to both access the nucleus and be reverse transcribed; the mRNA contains no nuclear access signals; and there are no known reverse transcription sites.