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March 7, 2023

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

Chairman Hardwick,

I write on behalf of the Biotechnology Innovation Organization (BIO) to express strong opposition to House Bill 1169, legislation requiring disclosure of the contents of certain health care products and genetically modified food.

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States – including in Missouri - and more than 30 other nations. BIO members are involved in research and development of innovative healthcare, agricultural, industrial, and environmental biotechnology products.

Drug warning labels and prescribing information must comply with federal regulations and receive approval from the Food and Drug Administration ("FDA") before going to market. When new evidence comes to light that a drug on the market may be associated with a scientifically validated risk of harm, a drug manufacturer may add or strengthen existing warning labels without first obtaining FDA approval, in accordance with so-called "Changes Being Effected" or "CBE" regulations.

Absent new evidence or other material safety discoveries, FDA-approved drug labels cannot be changed by the manufacturer without comprehensive scientific justification made to FDA. As such, ancillary labeling requirements under state law are generally preempted. In accordance with the Supreme Court's decision in *Merck Sharp & Dohme Corp. v. Albrecht*, where a manufacturer can provide evidence that FDA would not approve a state-required label change, such state changes will be preempted. In the case of HB 1169, the proposed state requirement bears no relation to a safety or efficacy claim that would otherwise merit a label change by FDA.



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Since the bill's definition of "genetically modified" is so broad and sweeping it would include genetically engineered crops used to produce food. A 2016 federal law establishing a national standard for disclosure of bioengineered food also precludes state and local governments from adopting their own standards for labeling of food with genetically modified content. HB 1169 clearly violates the 2016 law's preemption provision.

For these and many other reasons, BIO strongly opposes HB 1169 and urges you too as well. We appreciate your time and consideration and urge you to contact me at [pplus@bio.org](mailto:pplus@bio.org) if you have any questions regarding this matter.

Sincerely,

Patrick Plues  
Vice President, State Government Relations

cc: The Honorable Dean Plocher, Speaker, Missouri House of Representatives