Michigan Manufacturers Association

MEMO

TO: **Michigan House Committee on Judiciary**
FROM: **David Q. Worthams, Director – Employment Policy**
DATE: **October 25, 2023**
RE: **Senate Bill 410 – OPPOSED AS INTRODUCED**

On behalf of the nearly 1,800 members of the Michigan Manufacturers Association (MMA), I write today to express our opposition to Senate Bill 410, a bill that will remove the immunity for a drug manufacturer from product liability.

The role that the United States Food & Drug Administration (FDA) plays in reviewing, assessing, and approving the safety of a pharmaceutical drug cannot be understated. Their work was essential when the vaccines for COVID-19 were developed here in Michigan. The agency worked tireless to balance the pressing needs of addressing the pandemic, and of those patients in need of the vaccine and treatments for the disease, against the need to ensure that these products were indeed safe and effective. The work involved goes well beyond any suggestion that it is just a perfunctory stamp of approval.

Additionally, it is important to remember that MCL 600.2946 does not provide a "blanket defense." This section does not provide "complete immunity." The section provides that a drug manufacturer is not liable "*if the drug was approved for safety and efficacy by the United States food and drug administration and the drug and its labeling were in compliance with the United States food and drug administration's approval at the time the drug left the control of the manufacturer."* Intentional withholding of information from the FDA, misrepresenting information concerning the safety of a drug, or making an illegal payment to gain FDA approval voids the immunity.

Or, as Cary Silverman of the American Tort Reform Association (ATRA) put it in his testimony from October 5, 2023, "… if a company did what it was supposed to do, and the regulatory process worked as it should, an FDA-approved drug would not be found unsafe or defective in its design or warning."

Admittedly, Michigan is the only state with such a broad drug manufacturer liability shield and considering ways to amend this language, rather than a complete repeal, is something worthy of debate. Including language that provides for a rebuttable presumption that a medication is not unreasonably dangerous if it was approved by the FDA is an approach that places Michigan's act more in line with similar statutes from states like Colorado, Kentucky, Tennessee, Utah, and Wisconsin, among others. We believe adding such language to Senate Bill 410 strikes the right balance between protecting public health and promoting pharmaceutical innovation in the state.

Based on these reasons, MMA opposes Senate Bill 410 as introduced but we look forward to participating in additional discussions on amendments to the bill.