April 19, 2023

Rep. Julie Rogers
Chair, Health Policy Committee
Michigan House of Representatives
PO Box 30014
Lansing, MI 48909-7514

Rep. Rogers,

MichBio, as the statewide life sciences trade association, and its biopharma members share in concerns about the affordability of prescription drugs and cost of health care. However, we're alarmed that HB 4409 will harm our ability to afford the costly and time-consuming process of bringing new therapies to market.

HB 4409 would require biopharmaceutical companies to publicly disclose all sorts of proprietary, competition-sensitive and confidential information about a drug's research-to-market expenses.

On its face, this may seem like a simple and straightforward solution to address drug costs. However, the legislation assumes that a reasonable price for a particular drug could be determined if consumers better understood the costs associated with developing, manufacturing, marketing, and selling that drug. In reality there is no direct line to follow from such expenses to the patient's out-of-pocket costs.

The proposed reporting requirements would be especially burdensome on the engine of biopharmaceutical innovation — our biotech startups and emerging companies. Indeed, the majority of Michigan's biopharmaceutical sector consists of pre-revenue companies with less than 50 employees whose drug candidates have yet to reach the market.

These companies must use their limited resources as efficiently as possible to speed the discovery of treatments that can improve the lives of patients, and to reinvest in future innovation. Tracking the necessary data contained in this proposal on the presumption that the biotech will ultimately bring the drug to market or be acquired, and the data made available to the acquiring company, will divert scarce resources to accounting and compliance activities that could be better used on developing therapies that patients need.

HB 4409 doesn't understand the R&D process and focuses naively on costs associated with a single drug. Pharmaceutical companies often maintain a portfolio of R&D initiatives that are intertwined. It's not that simple to track a single drug candidate's cost through the R&D process. This is so because of the often-amorphous nature of development expenses, and the difficulty in assigning concrete scientific credit for the innovation associated with a drug's approval to various failures or insights gained from other research and disease areas. The determination becomes even more complicated when you consider partnerships, acquisitions and other third-party relationships that are often covered by confidentiality agreements.

And so, in a perverse manner, HB 4409 threatens Michigan's bio-innovation ecosystem. The only way small research-intensive companies survive is because investors, including large pharma companies, are willing to take huge risks and put significant financial resources behind our ideas. Losing such funding because of burdensome policies as proposed in HB 4409 will cause existing companies to leave Michigan and/or technologies discovered here will be commercialized in more business-friendly regions. That would mean high-wage job losses and lower economic output.

The biopharma industry welcomes an honest dialogue about the drug prices in the greater context of our total health care system. Our shared goal should be to design an economically sustainable system that ensures patient access and promotes biomedical innovation. Passage of HB 4409 will do nothing to promote this dialogue and instead will serve only to add more risk to our already perilous business model and dampen the attractiveness of investing in Michigan's biopharmaceutical companies.

Lastly, and most importantly, HB 4409 will do nothing to help patients better understand their drug costs as it does not meet patient-first priorities. Specifically, the legislation does not address transparency in the pharmaceutical supply chain like insurers nor PBMs (Pharmacy Benefit Managers). Out-of-pocket costs are directly related to how insurers allocate expenses to patients and families. Similarly, PBMs who act as middlemen receive rebates from the manufacturers intended for patients. In neither case do patients have transparency into how those are structured, nor do they receive the intended benefit in the form of lower out-of-pocket costs. These are the practices that need to be addressed through meaningful transparency that gives patients accountability and real relief at the pharmacy counter.

For all the above reasons, MichBio and its members are opposed to HB 4409.

Sincerely,

Stephen Rapundalo, PhD
President and CEO