Please Vote No on Colorado House Bill 18-1009

BACKGROUND*:*

HB18-1009, Diabetes Drug Pricing Transparency Act of 2018, sponsored by Rep. Roberts and Sen. Donavan would require drug manufacturers and pharmacy benefit managers to submit annual reports to the state board regarding drugs used to treat diabetes that are subject to price increases of certain percentages. Additionally, it would require that nonprofit organizations advocating for patients with diabetes or funding diabetes medical research that receive contributions from certain diabetes drug manufacturers annually report those contributions.

REASONS TO OPPOSE:

- HB18-1009 would stifle innovation of future diabetes therapies for the patients in need, thereby threating access to critically important treatments and negatively impact patients in Colorado.
- HB18- 1009 forces drug manufacturers to disclose proprietary and competitively sensitive business information.
- HB18- 1009 requires reporting that is not protected and is duplicative to what is already being reported in protected security fillings.
- HB18-1009 requires nonprofit organizations that advocate on behalf of patients or funds medical research to disclose contributions received from a manufacturer could be detrimental to research activities.

THE FACTS AND VALUE OF MEDICINE:

- Cost and affordability of medicines are important, but spending on medicines is not the primary driver of health care cost growth. The significant cost savings that medicines provide to the overall health care system is often ignored. Medicines lead to fewer physician visits, hospitalizations, surgeries and other preventable procedures – all of which translate to lower health care costs.

- In fact, if all non-adherent patients with diabetes were to become adherent, 341,000 hospitalizations and 699,000 emergency room visits could be avoided annually, resulting in nearly $5 billion of medical savings.

- Unlike other healthcare services, there are not wide variations in regional pricing of prescription drugs. The Centers for Medicaid and Medicare Services (CMS) reported that “there exists little variation in drug ingredient prices across… regions” but that reimbursement rates to providers for medical services can vary by nearly 300% across regions.1

TRANSPARENCY FOR THE INDUSTRY:

- The transparency measures in HB18-1009 undermines free-market competition. We to examine the entire healthcare sector holistically, which would help patients understand the manufacturers, insurers and pharmacy benefit managers role in determining patients’ out-of-pocket costs. HB18-1009 would not accomplish this goal or help the patient.

- Forcing companies to itemize their input costs for the development of a particular drug (like for diabetes) will not **lead to a better understanding of any individual drug’s pricing**. However, doing so will chill investment in future innovation by signaling an artificial price constraint on the few medicines that secure FDA approval.

- The data and reporting that HB18-1009 requires is difficult to capture because the R&D process is long-term and manufacturers pursue research efforts that include many failures before the development of one FDA-approved drug. Therefore, the reporting of the drug development costs required by HB-1009 would not be reflective of total investment because of the long-term nature and process to get a drug to market and is duplicative to what is already being reported in protected security fillings.

[1] MaCurdy T, et al. Geographic Variation in Drug Prices and Spending in the Part D Program. Centers for Medicare & Medicaid Services’ Office of Research, Development, and Information (ORDI). August 2009.

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- Non – profit reporting: At a time when the public is relying on services provided by nonprofit organizations that advocate on behalf of patients or fund medical research, the state should not create perceived obstacles that prevent nonprofit organizations from receiving funds for activities that positively impact patients. Furthermore, this component of the legislation violates current law. According to the Internal Revenue Service, "A tax-exempt organization is generally not required to disclose publicly the names or addresses of its contributors set forth on its annual return, including Schedule B." IRS regulations specifically exclude this information from the definition of "disclosable documents."[i]

CURRENT PROCESS

- Biopharmaceuticals are among the *most heavily regulated industries* in the healthcare sector.
- From discovery through FDA approval, *developing a new medicine on average takes at least 10 years and is estimated to cost $2.6 billion*. Less than 12% of the candidate medicines that make it into a Phase I clinical trial will be approved by the FDA. [2]
- When calculating the cost of research and development into one medicine, you must consider the cost of failures. Failure to recognize the expense associated with these results in an inaccurate calculation of the investment biopharmaceutical companies are making. *Accounting for these related discovery costs could be nearly impossible.*

CONCLUSION:

Our industry is committed to ensuring that patients have access to breakthrough therapies and the needed medicine, but HB18-1009 does not help accomplish this goal. Innovative medicines save and extend lives, improve quality of life and drive value to patients and the healthcare system as a whole. Access to these innovative medicines is key to many patients' survival. HB18-1009 stifles innovation and ultimately will not help patients most in need.

WE RESPECTFULLY URGE THE LEGISLATURE TO REJECT HB18 - 1009

[i] Public Disclosure and Availability of Exempt Optimizations Returns and Applications: Contributors' Identities Not Subject to Disclosure. IRS. https://www.irs.gov/charities-non-profits/public-disclosure-and-availability-of-exempt-organizations-returns-and-applications-contributors-identities-not-subject-to-disclosure.

[2] http://csdd.tufts.edu/news/complete_story/pr_tufts_csdd_2014_cost_study