Biotechnology Innovation Organization

February 28, 2018

The Honorable Joann Ginal, Chair
House Health, Insurance & Environment Committee
State Capitol
200 E Colfax
Denver, CO 80203

Dear Representative Ginal:

The Biotechnology Innovation Organization (BIO) respectfully opposes HB18-1260, which would enact various reporting and notification requirements for biopharmaceutical manufacturers that increase the list price of their products beyond a specified threshold or introduce new products with a list price above a specified threshold. BIO is concerned that through these requirements this bill will impose a form of price control that will scare away investors and disproportionately harm small biotech companies.

Artificial price controls will upset the innovation ecosystem that allows biotechnology companies to take risks in pursuit of new treatments and cures. Of nearly 5,400 clinical programs currently underway globally, 70 percent are led by small companies. Small start-ups and small research institutes are the engine of biotech innovation, and they rely heavily on outside investors to fund their research. These companies turn primarily to angel investors and venture capital firms, as well as larger pharmaceutical companies, to finance some of the most significant breakthroughs benefiting patients. For these investors, biopharmaceuticals are a risky sector: of the thousands of potential new therapies explored, only a small handful make it to the clinical trial stage, and of those that do begin clinical trials, 9 out of 10 do not succeed. Investors expect to recuperate losses and a reasonable return on investment, and these calculations are not performed on individual therapies in a vacuum—the ROI on successful therapies must make up for the failures as well.

Larger, more established companies use a similar formula for funding their ongoing research. But instead of relying on outside investors, they use revenues from existing therapies to finance R&D for the next wave of medicines. In fact, the biopharmaceutical sector has the highest rate of reinvesting its revenues among all industries.

This bill incorrectly assumes that an innovative therapy's price should only reflect the input costs for that product alone. If innovative biopharmaceutical companies only priced medicines based on the cost to develop each particular compound,

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almost all innovation would stop. The cost of R&D for failures must be spread out or there is no incentive to try for something that isn't a guaranteed success.

Policies that discourage market-based pricing or punish biopharmaceutical companies for bringing new therapies to market that are priced to sustain innovation will undoubtedly scare off investors and result in a devastating blow to small biotech companies' ability to secure funding for their research. While HB18-1260 does not enact direct price caps on biopharmaceuticals, the bill imposes a form of price control by discouraging price increases and subjecting manufacturers to negative consequences when they do increase prices.

The notice and reporting requirements contained in HB18-1260 would have negative consequences for biopharmaceutical companies and are inconsistent with meaningful transparency that could benefit patients and payers. This bill proposes to require biopharmaceutical manufacturers to report information that is proprietary and may be subject to separate confidentiality requirements. For example, this bill requires manufacturers to report marketing and pricing plans used in the launch of new drugs, specific factors used in determining price increase decisions, and acquisition prices of specific products. Our members consider much of this information trade secrets and we oppose requirements to publicly report information that will harm our members' ability to compete with other manufacturers and effectively negotiate with purchasers. There is nothing in this bill that protects the confidentiality of the information reported to private payers or the State, and in fact this bill specifically prohibits aggregating data reported by manufacturers, despite the fact that it requires the aggregation of information reported by health insurers.

We are also concerned that this bill's requirement to provide advance notice of price increases would have serious unintended consequences for the drug supply chain. The substantial advanced notice would provide enough time for wholesalers, hospitals, pharmacies, large provider networks, and buying groups to engage in stockpiling activity in advance of a price increase, which would disrupt the availability of medicines not only in Colorado, but nationwide. This problem is particularly sensitive for biologic medicines that often have limited distribution and cannot respond to sudden shifts in demand.

All of the above requirements—and their negative consequences—would not be triggered by changes to the price actually paid by health plans and pharmacy benefit managers. Instead, this bill only looks at Wholesale Acquisition Cost (WAC), the "list price" of a medication. A drug's list price is a starting-off point for negotiations between manufacturers and payers. All institutional payers receive significant discounts and rebates off the WAC, averaging about one third of all drug spending.

Year after year, data shows that the "net price" after rebates and discounts is 30 to 40 percent less than the list price. So while a 10 percent increase would trigger a notice under this bill, the actual increase to a payer may only be two or three percent. And this bill does not require a health plan or PBM to notify a purchaser

what the net price increase for the medication is, or if the WAC price increase will have no effect on a purchaser because a PBM negotiated price protections with the manufacturer.

BIO members are focused on comprehensive and sustainable solutions to improve patient access to medicines, while maintaining our steadfast commitment to investing in the hard work of innovation. We welcome a holistic debate about the value of innovative medicines, and are committed to exploring how value-based approaches to payment can facilitate smarter healthcare spending. However, as HB18-1260 is currently structured, it would harm innovative biopharmaceutical manufacturers yet provide no meaningful information to patients, payers, or policymakers. Health plans, pharmacy benefit managers, drug wholesalers, pharmacies, hospitals, and buying groups exercise direct control over both drug prices and related rebates and discounts. Many of these pricing structures are negotiated and paid in secret, and yet are not included in this bill's transparency provisions.

For these reasons, we respectfully oppose HB18-1260. If you have any questions, please do not hesitate to contact me at bwarren@bio.org or (916) 606-8016.

Sincerely,

Brian Warren
Director, State Government Affairs
Western Region

cc: Members, House Health, Insurance & Environment Committee