January 28, 2020

MassBio
MASSACHUSETTS BIOTECHNOLOGY COUNCIL

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Massachusetts Biotechnology Council
300 Technology Square, Eighth Floor
Cambridge, MA 02139

The Honorable Cindy Friedman
The Honorable Dan Cullinane
Joint Committee on Health Care Financing
State House
Boston, MA 02133

Re: Drug Industry Provisions of H. 4134

Dear Members of the Health Care Financing Committee:

On behalf of MassBio, our Board of Directors and our member organizations, please accept this letter as MassBio's written testimony regarding H. 4134, An Act to Improve Healthcare by Investing in Value (the "Bill"). MassBio represents over 1,200 life sciences companies, academic institutions, service providers and patient organizations, the majority of which are directly engaged in the research, development and manufacturing of innovative products that solve unmet medical needs for patients around the world.

MassBio's General Principles re: HPC Drug Pricing Proposals

For reasons set forth below, MassBio opposes Sections 7 and 37 of the Bill. Section 7 would establish newly instituted, company-specific proceedings before the Health Policy Commission ("HPC") with respect to recently approved drug products available in the commercial market with a gross, per-patient cost greater than $50,000. Under the Bill, manufacturers of such products, upon referral to HPC by the Center for Health Information Analysis ("CHIA"), are expected to justify specific product pricing, as well as drug price transparency disclosures, without any protections against the mandatory submission of proprietary and confidential information other than a public records law exemption. If enacted, this proposal, when added to the newly enacted drug pricing provisions set forth in M.G.L. c. 6D, s. 8A and M.G.L. c. 118E s. 12A, would establish the Commonwealth as one of the most highly regulated states for the biotechnology industry in the country. We approach the Bill and any other significant legislation regulating our industry with the following general principles in mind, and we respectfully urge you to consider them as you engage in this important debate.

A. Any state-sanctioned health technology assessment (HTA) procedures must include the patient perspective, appropriate transparency on valuation methodologies, and a process to ensure non-biased valuations.

From a policy perspective, MassBio opposes any drug pricing proposals tying HPC's pricing determinations to assessments by independent third parties designated by HPC or other ambiguously defined, or undefined, measures of value, without any further guidance, protections for patients, or rigorous transparency about valuation methodologies. The lack of any valuation standards would give broad and excessive discretion to HPC for its pricing determinations and risks the introduction of value frameworks that may be inappropriately biased or incomplete, or that fail to take into account the specific characteristics of certain patient populations. Indeed, although the topic of drug pricing has been hotly debated by policymakers, industry, patients, payors, academics and others in recent years, there is no drug price valuation methodology we know of that has achieved anywhere near universal acceptance among these and other health care stakeholders. Yet, the Bill appears to assume that HPC can conduct such valuations fairly and accurately. The lack of such generally accepted standards, when considered in light of the controversies surrounding present valuation methodologies, will only subject the state's

value determinations and associated public reports to legitimate skepticism. What's more, the absence of any standards guiding HPC in the application of valuation methodologies (either in the Bill itself or available through other means) would effectively prohibit any meaningful review of those value determinations in any appeal proceeding.

In sum, we are very concerned with proposals such as Section 7 of the Bill that grant the Commonwealth novel, and practically unlimited, authority to investigate the biopharmaceutical industry in connection with prices that are deemed excessive, based on state laws that lack any specific guidelines or other standards for such valuations.

B. We oppose any new HPC authority over manufacturers in excess of its current, collaborative role as a monitor of health care costs.

The Bill authorizes HPC to request transparency disclosures of any information from manufacturers after a referral by CHIA (see Section 20), without regard to whether such information is proprietary or confidential, or publicly available. This broad transparency authority stands in sharp contrast not only to recently enacted transparency laws in California (SB17) and Connecticut (PA 18-41) (under which these states can request only publicly available pricing information from manufacturers), but also to HPC's current authority over payors and providers in connection with health care or premium pricing decisions by these entities. HPC, as originally constituted under Chapter 224 of the Acts of 2012, was not expressly authorized to engage in health technology assessments relative to pricing in the health care market, including entity-specific pricing investigations of healthcare providers, or to seek broad categories of price justification disclosures from healthcare entities. Currently, no other healthcare entity is required to justify product or service-specific pricing to HPC by the disclosure of an unlimited range of confidential and proprietary information on the threat of significant penalties. The Bill's proposals to inflict such uniquely significant regulation on the biotechnology industry in particular is unfairly punitive and, particularly given the limited share of overall health care costs in the Commonwealth driven by drug spend, bears no reasonable relation to any meaningful healthcare cost control policy.

C. We oppose any drug price transparency requirements based on unlimited authority to request any information on pricing on the threat of significant penalties.

MassBio has consistently agreed with calls for more transparency across the healthcare system. We and our member companies have come to the table over the past several sessions to propose reasonable and workable transparency measures across all healthcare sectors, including payors, manufacturers, and PBMs. We continue to be committed to engagement with policymakers for the purpose of reaching transparency solutions that balance the need for patients to be well-informed about the cost of treatments, but also avoid upending the ability of our member companies to innovate and develop the much-needed treatments and cures of the future. The broad transparency authority granted to HPC in the Bill does not meet this test, as it unreasonably subjects our member companies to disclosure requirements that threaten to uncover confidential, proprietary, and competitively sensitive information, as well as information that is unduly difficult or even impossible to calculate – all on the threat of significant penalties. We are very concerned that without more specific and meaningful guidance in this regard, Section 7 of the Bill would encourage HPC to embark on wide ranging and problematic efforts to require the disclosure of highly confidential or even unavailable information from our members that may bear no relation to any reasonable drug price valuation methodology. We respectfully urge that the Committee consider more reasoned approaches to transparency requirements enacted in other states that balance the need for drug price transparency with the importance of preserving a level industry playing field on which world-leading innovative drug development can continue to thrive.

D. MassBio opposes draconian measures to inflict unnecessary, unfairly punitive, and excessive taxes on the biotechnology industry

Section 37 of the Bill proposes to penalize drug manufacturers for increasing the price of a drug by more than CPI +2% in a twelve-month period. This provision is both unnecessary given current market forces, and also ignores the reality of the true cost of prescription drugs after accounting for rebates and discounts.

In 2019, the average price increase for brand-name drugs was 4.9%. Drug price increases announced this year are averaging 5% as well. This is a significant reduction in average price increases from years prior and was done without any government intervention. Further, the 5% average increase falls squarely in-line with recent CPI +2% calculations. Aside from the legitimate arguments that government should not be regulating drug pricing, these data show that the proposal is unnecessary.

What's perhaps more important to understand when considering the impact of price increases is that the list price of a drug is irrelevant to the actual cost of prescription drugs to the healthcare system. According to data from SSR Health, as analyzed by Adam J. Fein, Ph.D., CEO of Drug Channels Institute[1], net drug prices of brand-name drugs sold in the U.S., after accounting for all rebates and discounts paid out to third parties such as PBMs and payers, ***decreased*** in 2019 by 3.1%. In fact, net prices ***decreased*** 3.1% in 2018 as well.

However, decreasing net prices, while beneficial to overall healthcare costs, do not always benefit the patient as they can be exposed to out-of-pocket costs that are calculated based on a drug's list price. For example, patients who are still in their deductible may be paying the full list price for a drug until their insurance kicks in. Or, they may have coinsurance requirements which are a percentage of a drug's list price. The solution to this problem is not to penalize drug manufacturers for price increases but to make payers share the considerable rebates they are receiving directly with patients, so those patients can also benefit from decreasing net prices instead of it all going to payers and PBMs as profit.

Thank you for your consideration of the above comments. Please do not hesitate to contact me if you have any questions or would like to discuss these viewpoints further.

Sincerely,

Robert K. Coughlin

President and CEO, MassBio

[1] https://www.drugchannels.net/2020/01/surprise-brand-name-drug-prices-fell-in.html