The Biotechnology Innovation Organization (BIO)
Testimony in Opposition to Maryland House Bill 666
Maryland House of Delegates
Health and Government Operations Committee
February 23, 2017

The Biotechnology Innovation Organization (BIO) would like to convey our opposition to Maryland House Bill 666, which would require biopharmaceutical manufacturers to disclose specific information on cost inputs for "expensive drugs" as defined in the legislation and to provide 60-day prior notice of any anticipated price increase for products priced over a certain threshold. BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than 30 other nations. In Maryland, BIO partners with the Maryland Technology Council. Our joint members are committed to advancing science and improving the health and well-being of our planet through the use of biotechnology.

The stated goal of HB 666 is to provide transparency to the State and to patients on factors associated with the cost of certain prescription drugs in a broader effort to reduce healthcare spending. However, this legislation will have the opposite effect by interfering with the competitive market place and by placing overly burdensome reporting requirements on small and mid-sized manufactures. These small to mid-sized biopharmaceutical manufactures, which will be disproportionally impacted under HB 666, make up the majority of research-based life science companies in Maryland.

The proposed transparency requirements in HB 666 would interfere with the market-based ecosystem of the US healthcare sector.

The proposed transparency requirements in HB 666 call for manufacturers to publicly report a compilation of individual data points on the costs to develop and market an innovative therapy. Much of this information is sensitive and disclosing it may put the manufacturer at a competitive disadvantage, which then undermines the market-based system for prescription medicines. Further, certain economic and investment-backed data is subject to trade secret protections, and state abrogation of these protections could threaten the broader business economy in the State.

Moreover, the disclosure requirements in the bill do not provide adequate context for the complex issue of drug pricing. Pricing is based not just on manufacturers' costs, but also on market forces, an accounting of failed research programs, and an assessment of value that cannot simply be reduced to a line on a balance sheet. What is more, the proposed requirements fail to capture, and may actually interfere with, the market-based environment in which pricing decisions are made. This includes negotiations between manufacturers and payers that affect how a therapy is covered and reimbursed by public health programs and insurance plans.

The requirement that manufacturers provide notice to the State 60 days in advance of a planned price increase would disrupt the market by creating financial incentives for secondary distributors to enter the pharmaceutical supply chain, thus creating a "gray" market. Gray market distribution networks consist of a number of different companies, some doing business as pharmacies and some as distributors that buy and resell medicines to each other before one of them finally sells the drugs to a hospital or other health care facility. As the medicines are sold from one secondary distributor to another, the possibility of counterfeit medicines augmenting the supply of legitimate medicines increases, thereby threatening patient safety. This type of purchasing already causes great difficulty for hospitals. During medicine shortages, hospitals are sometimes unable to buy medicines from their normal trading partners, usually one of the three large national "primary" distributors, AmerisourceBergen, Cardinal Health, or McKesson. At the same time, hospitals are deluged by sales solicitations from gray market companies offering to sell the shortage medicines for prices that are often hundreds of times higher than the prices they normally pay.

Advance notification of price increases may also have the unintended consequence of increasing prescription drug prices. Such notification signals to competitors the opportunity to increase prices with better certainty, because they know in advance what their competitors are doing. In fact, certain portions of the Federal Antitrust laws were implemented to prevent just such a scenario. Such signaling can create an artificial price floor rather than a price ceiling.

Finally, if concern centers on the uncertainty of pre-approved drugs entering the marketplace and causing a payor "shock" in terms of budgets and coverage uncertainty, know that the FDA is already working with the manufacturer community to ameliorate these concerns. In recently released draft guidance, the FDA indicates that discussions with payors, formulary committees, and certain other parties surrounding basic information like pricing considerations, patient populations, and other important metrics regarding a drug not yet approved by the FDA is permissible.[1] Heretofore this was an area of communication fraught with uncertainty thereby commonly avoided by manufacturers. In essence, FDA has heard from the broader healthcare community regarding the need to have pre-approval discussions to help prevent marketplace distortion and has finally taken steps to facilitate them.

[1] Drug and Device Manufacturer Communications with Payors, Formulary Committees, and Similar Entities – Questions and Answers, Guidance for Industry and Review Staff. Available at: http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm537347.pdf

The proposed transparency requirements place undue burden on small, pre-commercial biotechnology companies.

These proposed transparency requirements are unduly burdensome, especially on the engine of biotech innovation. Small, emerging companies with only a few or no products on the market must use their limited resources as efficiently as possible to continue to supply the therapies patients need and to invest in future innovation. By requiring a series of data points, this bill will divert scarce resources to accounting activities for research that may never become marketable.

A significant portion of research and development is done by individual scientists, academic researchers, and small venture-backed companies. In most early stages of research, scientists investigate broad categories of molecules, painstakingly separating those that might be fruitful to further research from the vast majority that will not. These proposed reporting requirements would force researchers and scientists to incorporate burdensome accounting measures into their laboratory practices.

While BIO shares the Legislature's concern about the affordability of healthcare, HB 666 is not the answer. We are concerned that while HB 666 aims to increase prescription cost transparency and ultimately lower the price of medicines, it may actually do the opposite by eroding the competitive market place for prescription drugs and placing costly and onerous administrative burdens on small biotechnology companies with little to no resources to comply with the law. We thank the committee for the opportunity to register our opposition to HB 666 and look forward to working with you in advancing legislation that will truly benefit patients.

Respectfully Submitted By

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