



**Biotechnology Innovation Organization (BIO) Testimony
The Connecticut Legislature
Committee on Public Health
Testimony In Opposition To Senate Bill 445
March 6, 2017**

Representative Jonathan Steinberg, Co-Chair

Senator Terry Gerratana, Co-Chair

Senator Heather Somers, Co-Chair

Representative Prasad Srinivasan, Ranking Member

Public Health Committee

Connecticut General Assembly

Legislative Office Building, Room 3000

Hartford, CT 06106

The Biotechnology Innovation Organization (BIO) would like to caution legislators that incorporating “transparency” provisions in Senate Bill 445 that are not focused on ensuring patients and providers have access to information that is meaningful in the context of clinical and health insurance enrollment decisions will threaten patient access to needed therapies and the competitive marketplace. This, in turn, could lead to worse health outcomes for patients who rely on medicines targeted by the draft bill as well as increase healthcare costs overall (e.g., from increased hospitalizations, physician office visits, and surgical procedures).

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. BIO’s members develop medical products and technologies to treat patients afflicted with serious diseases, to delay the onset of these diseases, or to prevent them in the first place. In that way, our members’ novel therapeutics, vaccines, and diagnostics not only have improved health outcomes, but also have reduced healthcare expenditures due to fewer physician office visits, hospitalizations, and surgical interventions.

The goal of SB 445 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, if the provisions of the bill target a single stakeholder in the healthcare sector, are not focused on information that is meaningful in the clinical or health insurance enrollment context, or place burdensome reporting requirements on any stakeholder, the legislation will have the opposite effect. In particular, we caution the State to consider the potential impact of any bill on small to mid-sized biopharmaceutical developers, which will be disproportionately impacted under a bill that targets innovative, new-to-market therapies that have the potential to cure or improve upon existing

treatments for complex, chronic diseases. In the balance of this letter, BIO urges the State not to move forward with any legislation unless it meets the goals just identified..

Any transparency requirements considered for inclusion in SB 445 must not interfere with the market-based ecosystem of the U.S. healthcare sector.

Any provisions that would call for manufacturers to publicly justify the price of certain therapies by detailing the input costs to develop and market them can interfere with the market-based ecosystem that works to bring down prescription drug costs through robust private-sector negotiations. As an initial concern, BIO notes that much of this information is sensitive and disclosing it may put the manufacturer in a situation of telegraphing sensitive pricing metrics to competitors, which then undermines the market-based system for prescription medicines. Further, certain economic and investment-backed data is subject to both federal and state trade secret protections, and state abrogation of these protections could threaten the broader business economy in the State.

Any disclosure requirements that the State may consider as part of SB 445 must provide adequate context for the complex issue of drug pricing. Pricing is based not just on a manufacturer's 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. Moreover, any attempt at better understanding the existing marketplace must take into account mandatory rebates—including the minimum 23.1 percent rebate for Medicaid utilization—as well as the rebates and discounts that are robustly negotiated by commercial insurers in the context of both private and public health insurance. In fact, a recent study found that innovative biopharmaceutical manufacturers realize less than half of net spending on prescription drugs (i.e., 47 percent), with the remainder being realized by non-manufacturer entities in the supply chain and transferred by manufacturers to other stakeholders through retrospective rebates, discounts, and fees.¹

Additionally, the State should consider the impact that out-of-pocket costs have on patients' access to innovative therapies, which are dictated not by manufacturers but by the specific benefit structure offered by an individual patient's insurance plan. Research consistently demonstrates that cost sharing has an inversely proportional relationship to medication adherence: as cost sharing increases, adherence decreases, which, in turn, can have a negative impact on patient health outcomes and increase their overall healthcare costs (e.g., due to otherwise preventable hospitalizations, physician office visits, and surgical procedures).²

Finally, the State must consider and take into account the value of innovative medicines to patients—especially those who may have no other treatment options—or the societal impact innovative technologies can have—including increased productivity and decreased overall healthcare costs. For example, since 1980, the life expectancy for cancer patients has increased significantly, and over 80 percent of those gains are attributable to new treatments, including medicines.³ In the case of chronic myeloid leukemia (CML), the 10 year survival rate has increased from less than 20 percent to more than 80 percent as a result of treatment advances.⁴ Overall, studies have shown that gains in cancer survival are worth nearly \$2 trillion to our society, with more than 80 percent, possibly up to 95 percent,

¹ Berkeley Research Group, 2017, *The Pharmaceutical Supply Chain: Gross Drug Expenditures Realized by Stakeholders*, available at: http://www.thinkbrg.com/media/publication/863_Vandervelde_PhRMA-January-2017_WEB-FINAL.pdf (last accessed on March 2, 2017).

² Eddy, M.T., C. L. Cook, K. O'Day, S. P. Burch, and C. R. Cantrell. 2012. How Patient Cost-Sharing Trends Affect Adherence and Outcomes. *Pharmacy & Therapeutics* 37(1):45-55.

³ E. Sun, et al., "The Determinants of Recent Gains in Cancer Survival: An Analysis of the Surveillance, Epidemiology, and End Results (SEER) Database," *Journal of Clinical Oncology* 26, suppl. 15 (2008): Abstract 6616.

⁴ Yin, W., J. R. Penrod, R. Maclean, D. Lakdawala, and T. Philipson. 2012. Value of Survival Gains in Chronic Myeloid Leukemia. *American Journal of Managed Care* 18:S257-S264.

of that going to patients, family, and our economy as a whole.⁵ None of this economic productivity is captured in a singular look at input costs of drugs alone.

The State should ensure that any provisions included in SB 445 do not place an undue burden on small, pre-commercial biotechnology companies.

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, which unquestionably increases the cost and burden of internal corporate compliance programs, 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. Any proposed reporting requirements that force researchers and scientists to incorporate burdensome accounting measures into their laboratory practices risk diverting the scarce resources of these companies.

While BIO shares the Legislature's concern about the affordability of healthcare, we urge legislators to carefully consider what the impact of the SB 445 provisions will ultimately have on patients, providers, and the environment sustaining biopharmaceutical innovation. We thank the committee for the opportunity to register our concern with the approach to SB 445 and look forward to working with you in advancing legislation that will truly benefit patients.

Sincerely,

A handwritten signature in cursive script that reads "Patrick Plues".

Patrick Plues
Vice President
State Government Affairs

⁵ Lakdawala DN, et al. An economic evaluation of the war on cancer. Journal of Health Economics. May 2010. 29(3):333-346.