VIA ELECTRONIC DELIVERY

January 15, 2018

The Honorable Nancy Wyman, Chair, and
Members of the Cabinet
The Connecticut Health Care Cabinet
Program Management Office
PO Box 1543
Hartford, CT 06144

Re: Health Cabinet Recommendations on Drug Costs

Dear Lt. Governor Wyman and the Members of the Connecticut Health Care Cabinet:

I am writing to submit comments on behalf of the Biotechnology Innovation Organization (BIO) to highlight our concern regarding proposals being considered by the Health Care Cabinet (the Cabinet). 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 thirty 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 yield not only improved health outcomes, but also reduced health care expenditures due to fewer physician office visits, hospitalizations, and surgical interventions.

BIO welcomes the opportunity to work with the state to develop meaningful policies to ensure patient access to much needed affordable medicines. While we believe there are some positive policy changes considered in the report, we have deep concerns regarding many other policies the Health Cabinet is considering. Our concerns focus on the following:

1. **Drug transparency laws fail to ensure consumers have the information they need.**
2. **Creation of a statewide drug review board conflicts with FDA's authority, and limits consumer assistance, harming patients with growing cost-sharing obligations in their health coverage.**
3. **Use of a public utility model, which would stifle innovation and harm the drug development ecosystem.**
4. **A state-based Importation model, which would put patients at risk.**

At the outset, BIO would like to shed some light on the current state of prescription medicines in the United States, because, unfortunately, many popular press accounts focus an overly narrow view on the list prices of a small subset of innovative biopharmaceutical products, rather than focusing on the marketplace as a whole. A brief overview of the *complete* picture of the biopharmaceutical marketplace is helpful in framing the issue. Specifically, according to the trade association representing the generic drug industry in the

United States, almost 90% of prescription medicines dispensed in the U.S. are generic.[1] And with FDA's continued movement in approving commercially-available biosimilar medicines, the marketplace for lower-cost biologic products is rapidly expanding. In short, the amazing innovations seen in the biopharmaceutical marketplace over the past several decades are also rapidly matriculating to the lower-cost generic market.

Further, the innovative side of the biopharmaceutical marketplace is strong, but challenges exist. The cost of developing a new drug has increased exponentially since the 1970s. A recent study conducted by the Tufts Center for the Study of Drug Development found that developing a drug that gains market approval can take 10-years or longer, and cost roughly $2.6 billion.[2] There is a high failure rate in biopharmaceuticals research and development (R&D), so investments must take into account the funds spent on products that never make it to market. Furthermore, biopharmaceutical development is increasingly relying on outside private and public market capital as an investment source. Investors, however, have a range of diverse industries to choose from when making capital allocation decisions. Issues like government-imposed price regulations are significant detractions for the investment community when evaluating investment options.

The enormous resources required to sustain and drive forward the innovation ecosystem is reflected in the reality that the pharmaceutical industry spends significantly more than almost every other industry on R&D. On average, pharmaceutical companies spend 18.5 percent of revenue on R&D; when looking just at the U.S., one study found that, in 2013, 23.4 percent of domestic sales went to domestic R&D.[3] Complementing this research is data that demonstrates the pharmaceutical industry spent not only the most on domestic R&D annually but also globally, averaging $150 billion globally in 2015. The entire budget for the National Institutes of Health (NIH) was $30 billion.[4] The direct and indirect economic impact in the State of Connecticut is approximately $61.4 billion.[5] Currently, fourteen percent (14%) of the Connecticut workforce work in the life-sciences field.[6] The biopharmaceutical industry alone is currently conducting 1,275 clinical trials recruiting or in progress within the State of Connecticut.[7] In short, while the innovation necessary to drive development of new treatments continues, the process is increasingly more difficult – and more expensive. But hope for patients with previously untreatable diseases continues to rise.

Drug transparency laws fail to ensure consumers have the information they need.

The Cabinet's proposals suggest that the state may consider adopting a form of drug price transparency legislation modeled on other states. However, transparency bills typically

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[1] Association for Accessible Medicines, *2017 Generic Drug Access & Savings in the U.S. available at: http://accessiblemeds.org/sites/default/files/2017-07/2017-AAM-Access-Savings-Report-2017-web2.pdf*

[2] Lamberti M. and Getz, K. Profiles of New Approaches to Improving the Efficiency and Performance of Pharmaceutical Drug Development. Tufts Center for the Study of Drug Development. May 2015.

[3] Pharmaceutical Research and Manufacturers of America (PhRMA). PhRMA annual membership survey. Washington, DC: PhRMA; 2015, as reported here: http://phrma-docs.phrma.org/sites/default/files/pdf/2015_phrma_profile.pdf (last accessed March 10, 2017).

[4] NIH Website and EvaluatePharma Report, 2015.

[5] The Economic Impact of the US Bio-Pharmaceutical Industry: National and State Estimates, May 2016.

[6] Ibid.

[7] www.clinicaltrials.gov Search performed: January 12, 2018.

do not address the real problem of getting affordable medications to individuals, and they provide information that would be otherwise useless to the patient. They simply place additional burdens on manufacturers, all while increasing the cost of doing business at a time when most people are concerned about the cost of medications.

BIO believes any transparency bills ought to ensure that information is beneficial to the patients, not just listing arbitrary information to which the authors of the bills simply want answers. Information should tell patients such things as what their out-of-pocket (OOP) costs are, whether their drugs are on the plan formulary, or whether they have an opportunity to get the drug for less money than their copayment. Transparency requirements should also be holistic in nature, meaning transparency should not just be applied to one actor, but rather all actors in the health care continuum, including health plans, PBMs. Last, it should ensure that it does not hinder innovation in the healthcare marketplace. Unfortunately, almost all transparency legislation, including those that have passed in California, Nevada, and Vermont, fail these tests. Much of the information requested qualifies as a trade secret or proprietary data that would be protected by state and federal laws. This restricts the competitive marketplace.

Any policies, either through transparency or otherwise that require disclosure of the amount of money spent on research and development or other line-item would not benefit the average consumer, without the full context, because the average consumer cannot know or understand the significant risks and investment in bringing a drug from discovery through FDA approval and to market. Furthermore, we caution the State to consider the potential impact of any "transparency" bill on small to mid-sized biopharmaceutical developers, which will be disproportionally 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.

Creation of a statewide drug review board conflicts with FDA's authority, and limits consumer assistance, harming patients with growing cost-sharing obligations in their health coverage.

While BIO applauds efforts to tackle the issue of price gouging by "bad actors", the price gouging legislation in Maryland is currently under litigation by the Association for Accessible Medicine (AAM). States must understand that the economic ecosystem that fosters innovation requires a delicate balance of a variety of factors. The pricing of a drug is unique to every company and product. For example, a drug that has an FDA-required Risk Evaluation and Mitigation Strategies (REMS) may need to factor in heightened safety concerns and expenses for training into the price of the drug, whereas others would not. Some drugs receive accelerated approval while others do not, shortening the length of time it takes to get approved. Other drugs that treat rare diseases can cost much more to develop than others because of the high risk involved and the small population that ultimately would be using the product. Moreover, the cost of research and development can multiply exponentially the longer a clinical trial is ongoing. Some rare conditions with fewer patients can make enrollment in trials that much more costly and time-consuming. In an industry where only 5 out of every 5,000 compounds becomes suitable for preclinical testing, the cost of a drug must also reflect all the failures a company may face before finding the successful compounds for testing. Moreover, only 12% of all drugs in clinical trials ever make it to patients.[8]

[8] http://www.phrma.org/advocacy/research-development/clinical-trials#overview

Most of BIO's membership is made up of small, innovative biotechnology companies that believe deeply in their mission and their product under development. They sacrifice millions of dollars, often for decades before ever turning a profit, if at all. These time and dollar resources must also be reflected in the price of the drug, if that drug ever reaches the market. Pricing must also account for the 4,995 failures before the company discovers that successful drug compound. No other industry faces such incredible risk or invests as much. Across all industries, the biopharmaceutical industry re-invests the most revenues on research and development.[9] There is much misinformation regarding the biopharmaceutical industry. For example, often people think examining the "profit margin" is a good way to measure success of a company. But with such high rates of reinvestment compared to other industries, "profit margin" is a misleading. BIO believes a better metric is to examine the "return on equity" compared to other industries. When comparing these data, the biopharmaceutical industry ranked 45th across all major industries in 2015.[10]

According to the Cabinet's report, the DRB would, "determine if the prices are sufficiently unjustified in comparison to market norms and/or clinical value that it puts patient health at risk and therefore warrants referral to the Attorney General…for potential unfair trade practice violations."

The premise of this Board is flawed from the beginning, because it presumes that biopharmaceutical spending is growing at an unsustainable rate. When, in fact, it is growing far less than other national health expenditures. According to the Centers for Medicare and Medicaid Services (CMS), National Health Expenditures are growing at a rate of 4.3%, while spending on prescription drugs is growing at a rate of only 1.3%. Expenditures for hospital and physician growth grew at a rate 4.7% and 5.4%, respectively.[11] Moreover, prescription drugs in general only compose 10% of the overall health care dollar.[12] When high cost drug therapies such as the Hepatitis C drugs first went on the market, there was significant concern about the price tag, however, after rebates and discounts took effect and market forces continued to work, states have achieved heavy discounts. When coupled with the fact that these medications cure patients of the expensive and deadly disease, the overall savings to the health care system is significant. This was only possible because a competitive marketplace has been allowed to flourish.

However, the creation of the DRB essentially wants to put in place a cookie-cutter philosophy to pricing of prescription drugs products with arbitrary metrics. One drug may be the first in a new class of drug, especially when considering biologics or gene therapy, and be unique, such that there are no "market norms" for many new innovative therapies. Medical innovation is in a brave new world of personalized medicine and gene therapy. The suggestion that the DRB would have the expertise to determine if these drugs have a "clinical value that may put patients' health at risk," implies that the State's DRB would have better resources and expertise than the FDA. It also implies that the FDA would not be doing its job of approving new innovative medicines and ensuring the safety of the nation's drug supply. The FDA, which is considered the gold standard for drug approval agencies throughout the world, would never approve a product that they believe would put "patient health at risk."

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[9] Factset, BIO Industry Analysis, June 2016.
[10] Ibid.
[11] CMS, National Health Expenditures, Annual Percent Change, by Type of Expenditure: Selected Calendar Years 1960-2016. December 2017
[12] Analysis of 2016 National Health Expenditures Data, CMS. December 2017.

Eliminating Most Coupon or Discount Cards and Copayment Caps

Copay Coupons

BIO shares concerns regarding the growing burden on consumers for their prescription drug coverage, with the growing use of high deductible health plans as well as trends in cost sharing that continue to shift costs to consumers. Further, it has been demonstrated that the higher the prescription copayment, the higher the rate of prescription abandonment at the pharmacy counter. According to a study published in the *Annals of Internal Medicine*, patients with a $50 copayment are more than 4 times as likely to abandon their prescriptions than those with a copayment of $10.[13] This number could have staggering impact on medication adherence, which is so important to maintain or improving the quality of life and overall health. Lack of adherence can lead to increased hospitalizations and other acute care spending.

With generic substitution being on average 89% across the nation, it is important to find alternative ways for patients not using generics to affordably access those non-generic medications to ensure the quality of care is maintained at a high level. Biopharmaceutical companies have attempted to ease the financial responsibility for patients by implementing coupon or discount programs that may defray the cost of a high cost-sharing burden. Many of these patients face discriminatory pharmaceutical benefit designs that require them to pay for co-insurance rather than co-payments, particularly on specialty medications, which are much more expensive. Through no fault of their own these patients are forced to make decisions to go without their medication because they cannot afford a 50% co-insurance on a $500 or $1000 prescription drug. The state should not interfere with popular patient programs that help patients get their needed medicines. These same concerns ring true for programs provided by charities that help patients afford their cost sharing.

Copayment Cap

The Cabinet appears interested in potentially limiting the copayments per month. BIO believes this could be a positive move since specialty medication cost-sharing can run patients into the thousands of dollars per month. We are supportive of efforts that could improve medication adherence and reign in cost-sharing to help patients keep their health finances manageable.

Use of a public utility model, which would stifle innovation and harm the drug development ecosystem.

The Cabinet report also explores the possibility of regulating the biopharmaceutical industry like the public utilities. BIO is strongly opposed to this idea as the industry has great differences between it and public utilities. Utilities typically ensure the provision of resources, such as energy or water, to households, however, these resources do not typically require a great deal of continuous research and development, or have patents pending, on new forms of electricity or airwaves.

[13] Shrank, William, M.D., et al., "The Epidemiology of Prescriptions Abandoned at the Pharmacy", Annals of Internal Medicine, November 2010.

A strong innovative ecosystem is dependent upon companies having protections for their intellectual property and being able to price their products at a level that maintains not only a profit, but a profit large enough to satisfy the research and development costs to get to market. Any attempts by states to implement price controls on biopharmaceuticals, is likely to be defeated in the Courts. In 2007, BIO filed suit against the District of Columbia, to combat the District's egregious excessive pricing prohibition.[14] The Courts ruled that placing a cap on prescription biopharmaceuticals violates US Patent and Trademark law and thus, the Supremacy Clause of the US Constitution.

The basic premise is that patent law guarantees an innovator exclusive rights to develop, manufacture, and price an innovative product without the fear of competition during the exclusivity period. As part of the decision, the Court said that the "only limitation on the size of the carrot should be the dictates of the marketplace."[15] In other words, innovators should be free to price their products as much as the market can bear. The Courts also referenced the Congressional Record during debate of the Hatch-Waxman Act, the law that gave us the current patent framework we know today, and in doing so created the generic drug industry, and they said, "[p]atents are designed to promote innovation by providing the right to exclude others from making, using, or selling an invention. They enable innovators to obtain greater profits than could have been obtained if direct competition existed. These profits act as incentives for innovative activities."[16]

In short, the implementation of a public utility model for prescription drug industry would have a drastic and chilling impact on biopharmaceutical innovation. As noted earlier, the governmental spending on research is roughly 5 times less than the private sector. The government would not likely be able to make up for the reduction research and development in the private sector that could occur if such a regulatory scheme were adopted. There are currently more than 7,000 drugs in the biopharmaceutical pipeline, 74% of which are considered potentially first in class.[17] We must not stymy medical innovation when the industry is on the cusp of incredible breakthroughs in personalized medicine and gene therapies that could change the face of modern medicine.

A state-based Importation model, which would put patients at risk.

BIO is strongly opposed to any efforts to create a state-run importation scheme for safety and quality concerns. The FDA has said time and time again that it cannot guarantee the safety of prescription drugs imported from Canada. According to a 2017 report of the non-partisan Congressional Research Service (CRS), eighty percent (80%) of all prescription drugs sold in Canada are from foreign sources. Health Canada (HC), the agency in charge of ensuring the safety of Canada's drug supply, admits that while the facilities that import these drugs are subject to inspections, it only did 3 outside inspections in 2011, and 14 in 2014.[18] In addition, of the 442 domestic inspections in 2014 and 2015, i.e., inspections of

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[14] *Biotechnology Innovation Organization v. District of Columbia*, No. 2006-1593 (Fed. Cir. Aug. 1, 2007).
[15] Sarnoff, Joshua, "BIO v. DC and the New Need to Eliminate Federal Patent Law Preemption of State and Local Price and Product Regulation," *Patently-O Patent Law Journal*, 2007.
[16] Ibid., quoting Bio v. District of Columbia, 2007. (also referencing Slip Op. at 16 (quoting H.R. Rep. No. 98-857, at 17 (1984)).
[17] http://www.phrma.org/science/in-the-pipeline
[18] "Drug Regulation in Canada," Congressional Research Service, January 2017.

facilities within Canada, nearly 3100 "observations" were made that constituted mostly quality violations. Of that number, 1517 were categorized as "critical" or "major."[19]

It is clear from this report that Health Canada cannot guarantee the safety of its own drug supply, let alone those drugs shipped to the US. No amount of savings is worth risking the integrity of the U.S. drug supply, and subsequently, the health and safety of US citizens.

Reflecting these concerns, the US Secretary of Health and Human Services has had the authority to import drugs from other countries, as long as the public health and safety isn't jeopardized, and, if it would generate savings for the public. Yet, in the ten years the Secretary has had this authority, no administration has exercised it.

Value Based Contracting

The Cabinet's report did contain elements that BIO is encouraged to see. In particular, BIO believes that value-based contracting is an important tool for payers, both public and private, to handle costs in a way that ensures compensation for the value of the manufacturer's product, but demonstrates a certain amount of risk the manufacturer may be willing to bear. These types of arrangements are still new, and there are some legal questions that need to be resolved before they become common place, such as the impact on the Medicaid Best Price Statute and the impact on anti-kickback statute. Despite these challenges, BIO member companies are paving the way in these areas. We hope that these innovative payment arrangements will continue to grow.

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Thank you for the opportunity to comment on the Health Cabinet's report. Should you have any questions or comments, please do not hesitate to contact me at 202-962-9200.

Regards,

/s/

Patrick Plues
Vice President
State Government Affairs

[19] "Drug Regulation in Canada," Congressional Research Service, January 2017.