PhRMA

January 15, 2018

The Connecticut Health Care Cabinet
Program Management Office
PO Box 1543
Hartford, CT 06144

Via Electronic Mail

Re: Cabinet Recommendations on Drug Costs

Dear Governor Wyman, Director Schaefer, and the Members of the Connecticut Health Care Cabinet:

Thank you for the opportunity to provide input on behalf of the Pharmaceutical Research and Manufacturers of America (PhRMA) with respect to the Health Care Cabinet's proposals. We respectfully submit the following comments for consideration as the Cabinet prepares to submit final recommendations to the Legislature. We appreciate the Cabinet's efforts to thoroughly examine the complex issue of drug prices and its recognition that there are multiple players in the system that have an impact on costs. At the core of our comments is the goal of preserving incentives for innovation and a competitive market that will make patients' lives better and reduce costs in the system as a whole in the long run.

PhRMA represents the country's leading innovative biopharmaceutical research companies. Our members are devoted to discovering and developing medicines that enable patients to live longer, healthier and more productive lives. New medicines are an integral part of the health care system, providing prescribers and patients with safe and effective treatment options, and improving quality of life. PhRMA's members spent approximately $65 billion in 2016 to research and develop medicines[1]. In addition, the innovative biopharmaceutical industry contributes significantly to Connecticut's Medicaid prescription drug spend by providing nearly $676.1 million in rebates to the state in 2016.

We acknowledge that manufacturers have a role to play in working toward a solution, and we are looking forward to continued work with the Cabinet and the Legislature to achieve that goal. However, for efforts to have a positive impact on patients in Connecticut, a comprehensive approach that focuses on the health care system as a whole and a comprehensive approach to controlling health care costs is critical. For example, medicines lead to fewer physician visits, hospitalizations, surgeries and other preventable procedures – all of which translate to lower health care costs. New medicines are making crucial contributions to medical advances and changing the direction of health care as we know it.

PhRMA Supports Proposals that Help Patients Share in Discounts and Encourage Adherence

While we have concerns regarding a number of the Cabinet's recommendations, we acknowledge and appreciate that a number of priority recommendations recognize the complexity of the medicine

1 PhRMA member survey

distribution system and the role that other entities such as PBMs and insurers have on the burden ultimately borne by patients. A January 2017 Berkley Research Group study shines a light on the entities that benefit from drug pricing and that dictate drug coverage. The report found that that in 2015, brand biopharmaceutical companies realized just 39% of total gross drug spending, which is based off the list prices of medicines before rebates, discounts and fees are calculated. This is down from 41% in 2013 due to significant increases in the rebates and discounts paid to PBMs and payers. Increased rebates and discounts have largely offset increases in list prices and reflect the competitive market for brand medicines. Additionally, shifts in insurance design have resulted in a more significant financial burden on patients even as growth in rebates has kept price increases for payors modest.

The country's top three PBMs control patient access to nearly 75% of all prescriptions filled in the U.S. They leverage their market share to obtain deep discounts on medicines while driving utilization to the lowest cost therapies, yet patients often do not share in these savings. These other stakeholders – not manufacturers – determine how much consumers ultimately pay for a medicine and we are supportive, in concept, of recommendations that help patients share the savings being provided by manufacturers in the form of substantial rebates. In Priority Legislative Recommendation (d), the Cabinet discusses the unique circumstance in the prescription drug space in which a patient may pay significantly more than the PBM or health insurer's negotiated price for the drug when a deductible or coinsurance is part of the plan design. Manufacturers provide over $100 billion in rebates and discounts to payors each year[2] and patients should share in those savings.

The Cabinet correctly links the issue of high cost sharing with medication adherence and PhRMA is encouraged by the Cabinet's attention to this reality as well as proposals that would optimize adherence to medications such as Priority Administrative Recommendation (b). These efforts will have real, tangible impacts on patient health while providing significant savings for the system as a whole. Medicines provide great value to patients and society by saving and extending lives and preventing unnecessary hospitalizations and other costly health care services.

The U.S. health care system could save $213 billion annually if medicines were used properly. A substantial body of evidence demonstrates that better use of prescription medicines reduces spending on other medical care. For example, an article in *Health Affairs* found that just an extra $1 spent on medicines for adherent patients with congestive heart failure, high blood pressure, diabetes and high cholesterol generated $3 to $10 in savings on emergency room visits and inpatient hospitalizations.

Notably, the Congressional Budget Office has acknowledged that increased use of medicines among Medicare beneficiaries decreased other medical spending. And, researchers have found similar patterns across Medicaid populations. For example, research has shown that a 1% increase in prescription drug utilization decreases inpatient Medicaid costs by as much as 0.31%.[3]

The real and substantial impact of increased adherence on costs generally is an important example of why it is critical for Connecticut to not lose sight of the system as a whole. By impacting just one step of

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[2] Vandervelde A, Blalock E; Berkeley Research Group. The pharmaceutical supply chain: gross drug expenditures realized by stakeholders. 2017. http://www.thinkbrg.com/media/publicatin/863_Vandervelde_PhRMA-January-2017_WEB FINAL.pdf

[3] M. Christopher Roebuck, J. Samantha Dougherty, Robert Kaestner and Laura M. Miller Increased Use Of Prescription Drugs Reduces Medical Costs In Medicaid Populations Health Affairs 34, no.9 (2015):1586-1593.

the supply chain, patients will not be helped in the immediate term. And by discouraging and stifling innovation, patients and the entire health care system will certainly be harmed in the long term. PhRMA looks forward to continued discussions as to how best to address these complex issues in a way that will continue to provide value and innovation to the system as a whole.

Areas of Concern

Consistent with previous comments, PhRMA continues to have concerns that a number of the Cabinet's proposals will not achieve the desired goal. In fact, many of the proposals could have negative effects including disincentivizing innovation, reducing the choice of therapies available to patients, and raising instead of lowering costs, while increasing the State's administrative burden.

" Price Transparency" Modeled on Other State Approaches

We understand that the Cabinet is recommending an approach that is based on pieces of various efforts passed in other states, including a version of Maryland's "price gouging" statute, New York's Medicaid price cap statute, and advance notification to payors. Although painted as addressing "price-gouging" or "increasing transparency" which on the surface sound like positive efforts, these proposals could have a number of detrimental impacts and do not address what the consumer pays at the point-of-sale.

Components of Drug Pricing

There is no set formula for setting a drug's price – each company has different considerations for its business model. Yet, legislators and some policy makers have introduced legislation with onerous reporting processes based on their perceptions of cost drivers that may influence a drug's price. These proposals focus on disclosing "perceived components of drug pricing" – metrics that are difficult, if not impossible, to line out or attribute to a particular drug and have little meaning to consumers.

Specifically, PhRMA opposes disclosing perceived components of drug pricing in this fashion because 1) such disclosure does not account for a medicine's value to patients and society and such disclosure is a precursor to price controls, 2) such disclosure will not help a patient understand their price at the pharmacy counter which is set by the insurer, and 3) and although list prices are a required starting point for negotiating a drug's net price, these prices do not reflect trends in net pricing, the true price paid by the purchaser. Increasing the administrative burden on both manufactures and the State associated with reporting, analyzing, and compiling data that does not actually get to the heart of what a patient pays at the pharmacy counter, as well as creating an entirely new state entity to manage the effort, is counterproductive. Instead, other Cabinet recommendations that get to this core issue, such as premium impact (Priority Administrative Recommendation(a)) and out-of-pocket expense disclosure (Other Legislative Recommendations (a)) would more effectively achieve the goals of educating consumers and understanding the real impact of drug costs.

Further, if we are serious about moving towards a more value-based system, not just for payors but also for patients, taking a more holistic look across the drug supply chain is an important step. Instead, we are concerned that many of the proposals outlined by the Cabinet represent a first step to setting price controls which could greatly jeopardize patient access to needed medicines that offset other health care expenditures.

Advance Notice

The Cabinet has discussed requiring manufacturers to provide "advance notice" regarding launch prices and price increases to payors. This concept raises a number of concerns and is likely to have the opposite effect of what is intended. Disclosing such proprietary information chills competition and undermines beneficial market forces. In fact, the Federal Trade Commission has indicated that disclosure of proprietary information would not lead to lower prices but would likely lead to increased prices. Simply put, revealing competitors' pricing and discount information removes incentives to provide discounts in the marketplace. Further, the constitutionality of advanced notification requirements is questionable and is currently the subject of litigation in California.

Advance notice can also incentivize others in the drug supply chain, such as secondary distributors, to manipulate the supply of medications in order to maximize profit. Disruptions in supply resulting from stockpiling or "gray market" activities will have a negative impact on patients and likely lead to fewer, not more, savings.

It is important to recognize that negotiations between sophisticated private market entities already limit the impact of any price increase on a payor for the duration of the contract. Payors have the ability to insulate their businesses from price increases - such as through contracts that link a rebate requirement to the delta of the price increase. With respect to state Medicaid expenditures, companies must give the Medicaid program the "best price." Medicaid is further protected by a consumer price index (CPI) penalty that compounds with any price increase over CPI.

Prohibiting Coupons

Copay coupons provide a valuable source of assistance for many commercially-insured patients, especially those who are struggling to afford the increasing out-of-pocket costs associated with insurance coverage for their medications. Changes in insurance design have resulted in many patients facing very high cost-sharing—including coinsurance rates as high as 40%—which jeopardizes a patient's ability to stay on a needed therapy. It is also becoming increasingly common that patients must meet a deductible before any prescription drug coverage applies. In 2015, 46% of commercial health plans required a deductible for prescription drugs, double the number of plans with deductibles in 2012. This significant shift in plan design places an increasing burden on patients. Prescriptions filled in the deductible phase or with coinsurance accounted for 52% of patient out-of-pocket spending on all brand medicines. This figure reaches 90% for specialty medicines.[4] This is especially alarming because patients are paying full price for a medicine before they fully meet their deductible while payors are still collecting negotiated rebates and discounts on these medicines.

As patients increasingly are responsible for significant cost-sharing before receiving comprehensive coverage for their medications, the role of copay coupons and other forms of patient assistance becomes even more important. Prescriptions for brand medicines are more than twice as likely to be abandoned at the pharmacy by a patient in the deductible phase of coverage than brand medicines not filled in the deductible (23% versus 9%).[5] In fact, different subgroups of the Cabinet took different

[4] Amundsen Consulting analysis for PhRMA
[5] *Id.*

positions on the importance of copay coupons, with one workgroup proposing a ban while another recognized their value and encouraged patient education regarding the availability of such programs.

Further, with strict utilization management techniques being applied to many brand name drugs, patients are only receiving brand when medically necessary. As the Cabinet acknowledges, the often high cost-sharing that is associated with medicines subjected to utilization management may not reflect the rebates and discounts provided by manufacturers, so copayment assistance is a way that branded manufacturers help patients afford the medicines they need. We urge this balance to be considered in any proposal that would limit patients' access to these important assistance programs.

Lower Priority Proposals

The Cabinet seems to have acknowledged the real, substantive concerns associated with some recommendations, including treating prescription drugs like a public utility and importation. We continue to have serious concerns about these proposals, but appreciate the Cabinet's interest in further study by the Office of Health Strategy and look forward to further discussions regarding our concerns and potential alternatives that will better achieve the State's goals.

Public utility model

The Cabinet has suggested that prescription medicines be regulated like a public utility, with substantial cost controls that will stifle innovation and reduce access. Branded manufacturers hold patents on their innovative medicines pursuant to a statutory scheme Congress created to incentivize innovation. In the case of branded manufacturers, companies invest substantial resources to bring a medicine to the market, and in exchange, the manufacturer can obtain patents on the discoveries they make and a period of exclusivity during which generic competitors cannot enter the market. Any attempt at the state level to cap the price of a drug would interfere with these patent rights and likely would be preempted by federal law as found in the 2007 *Biotechnology Innovation Organization v. District of Columbia* case.

The innovative biopharmaceutical industry invests significant research and development and takes on much risk to bring a medicine to market. According to Tufts University, it takes 10 years and $2.6 billion to bring a medicine through the approval process. Only 12 percent of drug candidates that enter clinical trials receive FDA approval. Efforts to impart price controls on innovative manufacturers could chill the research and develop of new medicines by taking away the incentives that allow manufacturers to invent new medicines. Price controls also could severely reduce Connecticut patients' access to medicines as is seen abroad.

While innovative biopharmaceutical companies are awarded with limited patents to reward their significant discoveries and associated financial risk, it is important to note that medicines are the *only* part of the healthcare system where costs decrease over time for patients and states. When brand name medicines face brand competition within a therapeutic class or when a brand's patent expires and generic drugs immediately enter the market, prices drop, often significantly. Today, nearly nine out of ten prescriptions are filled with generic medicines that often cost pennies on the dollar, and from 2017 to 2021 alone, nearly $103 billion of U.S. brand sales are expected to face generic competition[6]. This

[6] IMS Data www.phrma.org/cost

market dynamic saves money for both patients and the healthcare system overall—we do not see savings like this anywhere else in the healthcare system.

Beyond savings that occur due to the transition from innovative to generic medicines, biopharmaceutical innovations also create savings across sectors of the health care market. For example, in 2014, a new drug came to the market that provided a cure for more than 90% of patients with hepatitis-C, eliminating a lifetime of hospitalizations, debilitating symptoms, and treatments with harsh side effects and replacing it with a complete cure in just 12 weeks. Often, patients with hepatitis-C needed liver transplants, which could cost almost $500,000. Since 2014, several new treatments have come to the market, further driving down the price of the medicine. Clearly, innovation and progress in the pharmaceutical industry means better outcomes and quality of life for patients and their families as well as reduced health care costs to patients and the system.

Importation

A state-operated importation scheme would undermine the important medicine supply chain protections established by the federal government, putting patients at risk. The United States' regulatory structure is the gold standard when it comes to ensuring the safety of our medicine supply. Without proper Food and Drug Administration oversight and enforcement of laws designed to protect patient safety—which importation schemes would undermine—there is increased potential for counterfeit or adulterated products to infiltrate the U.S. pharmaceutical supply chain, with life-threatening consequences.

The Secretary of Health and Human Services has had the authority to permit importation from Canada for well over a decade as long as a simple, common-sense test is met: 1) the imports pose no additional risk to public health and safety, and 2) the importation would generate savings for American consumers. To date, neither Democrat or Republican administrations have exercised this authority.

Without federal assurances of the safety and security of the medicine supply, a state-operated importation scheme will leave Connecticut residents at risk. Canadian authorities have expressly stated they are not responsible for the safety and security of medications being exported from Canada to the United States.

Furthermore, a state law allowing importation of drugs is likely preempted by federal law, as was the case with a 2013 Maine law that permitted importation of drugs from certain foreign-licensed retail pharmacies.

Thank you for the opportunity to comment on the Cabinet's recommendations and we look forward to continuing to work together to address these important issues.

Kind Regards,

Kelly A. Ryan

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