Your Generics and Biosimilars Industry

To: C/O Victoria Veltri,
Chief Health Policy Advisor
victoria.veltri@ct.gov
The Connecticut Heathcare Cabinet
Program Management Office

From: Ashlie Van Meter
Association for Accessible Medicines
Ashlie.VanMeter@accessiblemeds.org

RE: Association for Accessible Medicines' Comments to the Connecticut Healthcare's Draft Recommendations

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The Association for Accessible Medicines (AAM) respectfully opposes a portion of the Connecticut Healthcare Cabinet's (Cabinet) Draft Recommendations on Pharmaceutical Costs (Draft Recommendations). AAM is the nation's leading trade association for manufacturers and distributors of FDA-approved generic and biosimilar medicines. AAM is dedicated to improving the lives of patients by advancing timely access to affordable generic and biosimilar medicines. We are concerned that one of the Draft Recommendations would result in fewer drug choices and higher costs for patients in Connecticut.

AAM members provide more than 36,700 jobs at nearly 150 facilities, and manufacture more than 61 billion doses of medicine in the United States every year. Generic medicines represent more than 89% of all prescriptions dispensed in the U.S., but only 26% of expenditures on prescription drugs, saving patients and payers nearly $5 billion every week. The U.S. Department of Health and Human Services (HHS) last year concluded **"that generic drug prices are not an important part of the drug cost problem facing the nation."**[1]

In fact, generic medicines generated $253 billion savings in 2016 – including nearly $3 billion state of Connecticut alone. It is important to note that nearly half of all savings from generics go directly to the patients.

As proposed, the Draft Recommendations ignore major and important differences between brand and generic marketplaces. In doing so, the Draft Recommendations threaten to disrupt the generic marketplace that makes life-saving medicines affordable. While brand drugs see steady price growth over time, the price of a generic drug falls precipitously as competitors enter the market, often settling at 80 percent less than that of the brand. This creates a highly

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[1] [1] Office of the Assistant Secretary for Planning and Evaluation, Department of Health and Human Services, "Understanding Recent Trends in Generic Drug Prices." https://aspe.hhs.gov/pdf-report/understanding-recent-trends-generic-drug-prices

competitive marketplace in which many generic manufacturers make decisions on market entry, and exit more quickly and more often than brand manufacturers. While a single brand manufacturer makes a patented drug, and sets the monopoly price and defines its market, in the generic market, multiple generic manufacturers directly compete and regularly adjust prices to best react to market conditions, such as changes in supply costs, ingredient shortages, and other factors. Many of the largest generic manufacturers maintain portfolios of hundreds to even thousands of products. The Draft Recommendations fail to recognize these differences or account for the fact that generic medicines often operate on razor-thin profit margins, which are extremely susceptible to minor market changes, including the introduction of new regulations.

The Draft Recommendations Based Upon the Unconstitutional Maryland Legislation Must be Reconsidered.

Rather than addressing high prescription drug prices, the Draft Recommendations would just make the problem of unaffordable medicines worse for Connecticut patients and economy. Draft Recommendation 1a proposes to create a new Drug Review Board (DRB) "to investigate drug pricing decisions by manufacturers." This proposal appears to draw pieces of its enforcement from the Maryland law that is currently being litigated as unconstitutional. As the approach taken in Maryland, this Draft Recommendation allows the government to impose costs and regulatory burdens through enforcement from the state's Attorney General. This Draft Recommendation calls for the Attorney General to interfere in the generic marketplace when he or she receives a recommendation from the newly created DRB, thereby undermining the robust competition that currently exists in the generic pharmaceutical marketplace. The competition that this Draft Recommendation would inhibit is the very thing that works to keep generic drug costs low.

The DRB, as currently envisioned, does not consider the important role generics and biosimilars play in reducing costs for patients and the system. Connecticut is not the first state to consider such a review board. Las year, New York created a board designed to review products that drive Medicaid spending in the state. However, in developing that policy, the state of New York proactively decided to focus the board's attention on high priced products that account for significant state spending and explicitly exempted the generic market. The Draft Recommendation ignores the fact that generic drug prices continue to decline, while brand-name drug prices rise. The overall price of generics fell over 8% in 2016, and prices are down over 70% since 2008. Although generic drug prices can fluctuate up and down, they continue to rapidly drop on average. By subjecting manufacturers of generic drugs to draconian penalties when they are providing Connecticut with billions of savings each year, and in turn, failing to focus on the true cause of increased drug prices - brand-name prescription drugs - this Draft Recommendation would cause generic manufacturers to consider abandoning the manufacturing of certain products, reducing competition overall and threatening the savings realized by Connecticut residents.

In addition, this Draft Recommendation does not adequately define when a price is an "unjustified pharmaceutical prices or price increases." Given the vague standards set forth in the

Draft Recommendation, companies would perpetually be at risk of facing prosecution for price fluctuation of just pennies that can normally occur during the course of business within a competitive free market. Additionally, the Draft Recommendation makes no allowance for a manufacturer to make reasonable business decisions based on existing market dynamics.

The generics market has a downward price trend. In fact, one leading Pharmacy Benefit Manager's data **shows generic prices going down over 60% since 2008 when accounting for inflation. Comparatively, brand prices increased by over 50% in the same period.**[2] As proposed, the Draft Recommendations will discourage generic manufacturers from entering the market; that, in turn, would result in fewer health care choices for patients and higher costs for residents of Connecticut.

Rather than focusing on high drug prices, the Draft Recommendations lump generics in with brand manufacturers, and in doing so, detrimentally impact generic drugs, the class of medicines that saved Connecticut's patients and taxpayers nearly $3 billion in 2016. In addition to its policy flaws, the Draft Recommendations appear to violate the Dormant Commerce Clause of the Constitution by subjecting national sales agreements to Connecticut's standards.

AAM Request: Because the portion of the Draft Recommendation that would subject generic and biosimilar drugs to potentially arbitrary action from the Attorney General does not account for important market differences between brand and generic markets, AAM urges the Cabinet to fully exempt generic manufacturers and makers of biosimilars. Generic and biosimilar manufacturers already operate in a highly competitive marketplace that provides billions of dollars in savings each year for the Connecticut health care system, taxpayers and patients. Without an exemption for generic and biosimilar manufacturers, the Cabinet will reduce competition overall, and thereby, threaten the irreplaceable savings provided to Connecticut residents solely through generic utilization.

Please contact me at Ashlie.VanMeter@accessiblemeds.org if you have any questions.

Sincerely,

Ashlie Van Meter
Association for Accessible Medicines
Senior Director, State Government Affairs

[2] Express Scripts, Inc., "The Express Scripts Prescription Price Index." http://lab.express-scripts.com/drug-trend-report/trend-drivers/the-express-scripts-prescription-price-index