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WEDNESDAY, DECEMBER 2, 2015

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COMPTROLLER LEMBO, IN TESTIMONY TO CONGRESSIONAL DEMOCRATIC STEERING AND POLICY COMMITTEE: "INVESTIGATE AND REVERSE RUNAWAY PHARMACEUTICAL DRUG PRICES"

Comptroller Kevin Lembo, in written testimony submitted to the Democratic Steering and Policy Committee for a hearing today, detailed the consequences of a runaway pharmaceutical drug marketplace that threatens to obstruct patient care and overcome health care budgets across the public and private sectors.

In October, Lembo – who administers health benefits on behalf of more than 200,000 state and municipal employees, retirees and their dependents – called on Connecticut's congressional delegation to immediately investigate and act to reverse the root causes of these alarming pharmaceutical drug price increases.

The Democratic Steering and Policy Committee, co-chaired by Congresswoman Rosa L. DeLauro, held a hearing, "Ensuring Access and Affordability of Prescription Drugs, While Spurring Innovation," to further investigate the causes and possible solutions to concerning rises in pharmaceutical drug pricing nationwide.

Lembo submitted written testimony that detailed consequences experienced at the state level, and recommended areas of investigation and possible solutions to explore.

"These drugs – lifesaving, life-changing medications – are not yachts, private jets and other material icons of wealth reserved only for the privileged few," Lembo said.

Lembo pointed to published reports that highlighted an extreme example of a price spike for the drug Daraprim after the rights to the drug were acquired by Turing Pharmaceuticals.

"The headline rightfully grabbed significant attention – but the issues raised by this story are not isolated or unique," Lembo said. "They signal a more pervasive and intensifying trend in the pharmaceutical marketplace.

"The sharp rise in pharmacy costs comes at a time when we are seeing great success in limiting medical spending by promoting preventive care and chronic disease management through the state's Health Enhancement Program (HEP). The drastic increases in pharmacy costs are undermining our medical cost savings."

Lembo recently implemented new restrictions on the state plan to curb a rapid rise in unregulated compound drug prescriptions through the state health plan that have dramatically reduced state spending – by approximately \$2 million per month – on certain questionable medications.

Despite these and other efforts to manage health-care costs, Lembo said pharmaceutical costs continue to skyrocket due to several factors in the market.

"The factors behind rising pharmacy costs include market consolidation, new pricing models and outright profiteering. Projections indicate no future relief as pharmacy costs are expected to continue to rise at an exorbitant rate in the coming years. Meanwhile, pharmaceutical companies are recording historic profits.

"We applaud the profit motive in our free market society as a mechanism to efficiently distribute resources and drive innovation, but excessive profits can cause significant harm when applied unbridled to essential and lifesaving medicines in an uncompetitive marketplace. High costs are pushing certain treatments out of reach for some and, on a macro level, our society has fewer resources to expend on other important priorities."

Lembo said the issues plaguing the pharmaceutical market are twofold – and each will likely require distinct remedies. The issues are:

- significant price increases in certain traditional brand and generic medications, and;
- significant additional costs associated with the introduction and expanded utilization of new specialty drugs.

Generic and Brand Price Hikes

The state plan has experienced significant cost increases for non-specialty drugs – an unsustainable 16.9 percent – as a result of substantial price hikes in traditional brand and generic medications, Lembo said.

"The increased costs come at a time when we are seeing very little change in overall utilization for brand and generics – and the changes we are seeing should result in lower, not higher, costs," Lembo said.

For example, last fiscal year the state experienced a slight reduction in the utilization of brand drugs and a slight increase in the generic dispensing rate. Despite these encouraging utilization patterns, Lembo said the state still incurred significant additional costs driven by price hikes of long available traditional brand and generic medications.

As the extreme case involving the drug Daraprim demonstrated, companies have been buying up the rights to generic and brand drugs and then increasing prices.

"Industry consolidation has eroded competition in the market, which in turn allows pharmaceutical companies to demand higher prices," Lembo said. "Even worse, a significant backlog of applications to manufacture generic medications at the U.S. Food and Drug Administration (FDA) is contributing to the lack of competition and high prices."

Lembo urged the federal delegation to quickly:

- Strengthen anti-trust laws to limit consolidation in the pharmaceutical industry and ensure that adequate competition remains to drive competitive pricing in all drug classes; and
- Reduce the FDA backlog of generic drug approvals, and sharply reduce the review time of such applications, in order to swiftly introduce competition to consolidated markets.

"Additionally, the promise of lower cost generics only occurs when generics come to market after patent protection for a brand name drug expires," Lembo said. "Pharmaceutical company stall tactics have delayed the introduction of generic competition for some blockbuster brand drugs."

In Fiscal Year 2015, the state employee plan incurred significant costs for the brand drug Nexium as a result of a significant delay in the release of a generic version of the drug. The delay resulted in substantial costs for the state employee plan, which expended more than \$8 million that year for the brand name version when an available generic would have significantly reduced the costs to the plan.

"The combination of delayed approvals at the FDA and significant market consolidation has increased prices for generic and brand drugs as a result of reduced competition," Lembo said.

Specialty Drugs

"The specialty drug market poses its own significant challenges that are separate and distinct from those related to traditional brand and generic drugs," Lembo said. "The added costs resulting from specialty drugs, in large part, are for new innovative treatments that are often more effective than those previously available. As such, specialty drug manufacturers are adding real value to the medical system. Still, specialty medications are launching at much higher price points than similar specialty drugs released just three or four years ago – creating a significant cost burden for health plans and consumers."

Lembo detailed the effect of specialty drug cost increases on the state plan:

- Specialty drug costs for the state employee plan are increasing at an astronomical 54.7 percent.
- Specialty drugs accounted for just 1.2 percent of total prescriptions in Fiscal Year 2015, but 25.6 percent of total costs and the percentage is rising fast.
- At the current cost trend, specialty drug costs will increase to more than half of the state's total drug spend in just a few short years.

"All indications are that the trend will continue as the majority of new FDA approvals anticipated in the next four years are specialty drugs," Lembo said. "Many of these medications will bring much needed relief to individuals, but the runaway prices are unsustainable and must be addressed."

Significant investments have been made in the development of these new treatments, and better treatments like the new class of Hepatitis C drugs are saving lives and reducing long-term medical costs, Lembo said. However, not all specialty drugs have such clear medical cost savings, and yet the high prices are not limited to the Hepatitis C drugs. They can be found across the spectrum of specialty drugs.

Lembo said at least two current proposals should be thoroughly examined:

- Reducing the data exclusivity period from 12 years to 7 years for biologics (the exclusivity period refers to the time during which data used to obtain FDA approval is protected from use by generic manufacturers); and
- Allowing Medicare to use its market power to negotiate lower drug prices.

"Both should be thoroughly examined -- however, provisions should also ensure that negotiated Medicare prices serve as a reference price for the privately insured market," Lembo said.

"The State of Connecticut and health plans across the country are seeing unsustainable growth in pharmacy drug spending. The root causes of the increased costs include industry consolidation and delays in generic drug approvals that are allowing pharmaceutical

companies to demand higher prices for existing generic and brand drugs. At the same time, newly released specialty drugs are being priced significantly higher than those released only a few years ago as pharmaceutical manufacturers move to a "what the market will bear" pricing strategy.

"The rapid price increases are straining the state budget and, more importantly, placing significant burdens on consumers who need access to these medications. Swift action is necessary to infuse competition into the marketplace and institute strategies to control costs where competition is inadequate or impossible.

"I urge congress to fully evaluate the options available to put pharmacy spending back on a sustainable path."

