Generic Pharmaceutical Association

April 28, 2016

The Honorable Orrin Hatch
Chairman
Committee on Finance
United States Senate
Washington, DC 20510

The Honorable Fred Upton
Chairman
Committee on Energy and Commerce
United States House of Representatives
Washington, DC 20515

The Honorable Ron Wyden
Ranking Member
Committee on Finance
United States Senate
Washington, DC 20510

The Honorable Frank Pallone
Ranking Member
Committee on Energy and Commerce
United States House of Representatives
Washington, DC 20515

Dear Chairman Hatch, Ranking Member Wyden, Chairman Upton and Ranking Member Pallone:

The Generic Pharmaceutical Association (GPhA) is the nation's leading trade association for manufacturers and distributors of generic prescription drugs, manufacturers of bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic industry.

GPhA's core mission is to improve the lives of patients and the U.S. healthcare system by advancing timely access to affordable generic medicines. GPhA's members are leaders in providing quality and affordable treatments to patients.

On behalf of our members, we would like to take this opportunity to express our deep concerns regarding Section 602 of the Bipartisan Budget Act (BBA) of 2015 (P.L. 114-74). Section 602 of the statute amends the Medicaid Drug Rebate Program (MDRP) to impose a price increase penalty on non-innovator multiple source drugs, or generic drugs, similar to that paid for innovator drugs.

As you know, brand and generic drug manufacturers are required to enter into a Medicaid rebate agreement in order to be reimbursed. Brand manufacturers' base rebate is 23.1% of Average Manufacturer Price (AMP) and in addition, innovator drugs are subject to an additional rebate if the AMP for a given quarter exceeds the inflation-adjusted baseline AMP, which is usually the first full quarter after launch. Generic drugs are subject to a base rebate of 13% of AMP. Under Section 602 of the BBA, an additional rebate penalty will now apply to generics for price increases exceeding inflation for rebate periods beginning with the first quarter of 2017. By establishing separate base-level rebates for brands and generics, Congress historically has signaled recognition of the different dynamics associated with brand and generic markets. This new penalty provision, originally designed and implemented to control price increases for branded medicines during their periods of market exclusivity, fails to continue with that

recognition and instead adopts a policy that is inappropriate for the very different generic drug market dynamic.

The current attention to prescription drug prices was sparked by recent price increases among specialty medicines, as well as older, off-patent branded medicines that face little to no competition. However, as you know, recent studies[1] have shown that although brand drugs represent only 12% of all prescriptions, they account for 72% of all drug costs. And, according to the IMS Institute for Health Informatics, "medicines classified by IMS Health as "specialty" contributed $150.8 billion to the total spending on medicines in 2015, an increase of 21.5% over 2014."[2]

Nonetheless, this new generic Medicaid rebate provision, while described as protecting against unreasonable price increases, fundamentally serves to impede the natural market dynamics that allow generic drugs to be low priced, and could lead to potentially irreversible and unintended negative consequences for patient access to affordable medicines.

The generic marketplace operates in a much different way than the brand drug marketplace. As more generic competitors enter the market, the price of the generic drug falls precipitously, often to 80% less than that of the brand. This creates a thriving and constantly-changing marketplace in which generic manufacturers face ingredient cost and supply fluctuations to a much higher degree than a brand manufacturer. However, the new rebate penalty structure imposed by the BBA fails to recognize the fundamental market differences of the generic and brand business models. By applying a policy solution developed for brand manufacturers to the very different competitive market of generic drugs, this provision can increase costs, and endanger generic drug development and viability in the marketplace. The rebate also puts Medicaid beneficiaries, some of our nation's most vulnerable patients, in a position where they have fewer generic options than currently exist, which could lead to increased costs to the program and state budgets.

Importantly, recent data clearly shows that overall generic drug price trends have been downward:

- According to the 2015 *Generic Drug Savings in the United States*[3] report compiled by the IMS Institute for Healthcare Informatics on behalf of GPhA, **generic drugs accounted for 88% of all prescriptions dispensed in the U.S., but equaled only 28% of total drug spending.**

- In January 2016, the Department of Health and Human Services (HHS) Office of the Assistant Secretary for Planning and Evaluation (ASPE) released a comprehensive report, *Understanding Recent Trends in Generic Drug Prices*[4], and found that the generic drug market is "quite competitive" and that any price increases in that market are "sufficiently limited so they exert no sizable influence on overall drug spending." Most notably, the

[1] *Generic Drug Savings in the United States*
[2] *IMS Medicines Use and Spending in the U.S.*
[3] *Generic Drug Savings in the United States*
[4] *Understanding Recent Trends in Generic Drug Prices*

ASPE report stated, **"Our review of evidence strongly supports the conclusion that generic drug prices are not an important part of the drug cost problem facing the nation."** The report also found that "about two-thirds of generic products appear to have experienced price declines in 2014."

- A May 2016 report, T*rends in Retail Prices of Generic Prescription Drugs Widely Used by Older Americans*[5], conducted by AARP found that**, "Retail prices for generic drugs fell an average of 4% in 2013,** marking nearly a decade of consecutive years of decreasing generic drug costs. The annual retail price decreased for 203 (73 percent) of the 280 most widely used generic drug products."

- An August 2015 study by Drug Channels[6] comparing generic drug costs in the fourth quarter of 2014 and the first quarter of 2015 found that **75% of generic drugs decreased in cost, stayed the same, or increased in cost by less than 5%.**

- Express Script's December 2014 Drug Trend Report[7] found that **generic drug prices were 20% lower than a year earlier** whereas brand drug prices were 15.4% higher. An index of commonly used generic drugs shows prices decreased by 62.9% from January 2008 through December 2014. During that same period, a brand drug price index increased in price by 127.4%.

In fact, of the 14,000 generic drugs on the market, in the very limited circumstances where price increases have been noted, there have been various reasons for these occurrences, mostly attributable to the highly competitive environment in which generic manufacturers operate. For example, a sudden shortage of the active pharmaceutical ingredient (API) or facility closures may affect the cost of goods, leading to higher production costs for manufacturers. Meanwhile, current consumer protection laws already provide significant authority to punish genuinely unethical practices.

Further, even if a generic manufacturer seeks to enter a market to lower costs, applications are currently facing a 48-month average wait for approval at FDA, and even under the timeline goals of GDUFA I years 3 and 4, may still take more than 15 months (GDUFA metrics for years 3 and 4) for approval.

Imposing a CPI inflation-based Medicaid rebate penalty on the generic drug industry does not address any of these issues. Instead, it impedes the natural market-driven dynamics that have led to a robust generic drug industry with products 80-85% less costly than brands that have yielded U.S. healthcare savings of $1.68 trillion over the past 10 years[8].

Considering the unique market dynamics of the generic industry and the active pharmaceutical ingredient supply chain realities, this policy creates a disincentive for continued manufacturing of particularly low-margin and low-cost products that would be most affected by this rebate, and

[5] *Trends in Retail Prices of Prescription Drugs Widely Used by Older Americans, 2006 to 2013*
[6] *The Retail Generic Drug Inflation Slowdown: It's Real*
[7] *2014 Drug Trend Report*
[8] *Generic Drug Savings in the United States*

will increase the possibility of fewer competitors in some therapeutic areas. GPhA has detailed below a number of concerns that we feel need to be addressed before the implementation of this provision.

- By linking this rebate to the consumer price index (CPI) and Average Manufacturer Price (AMP), the provision inappropriately applies a brand drug model to the multi-source generic drug market.

- Generally, an important source of short-run AMP changes for generic drugs are changes in customer mix, not manufacturer prices increases. Such changes in the mix of sales for a manufacturer often affect the reported AMP even if prices charged to every customer remain the same. These fluctuations are a result of a dynamic and competitive generic market in which multiple manufacturers offer interchangeable products and customers regularly alternate suppliers in search of low prices and adequate supply.

- For example, a decline in sales to (lower-priced) high-volume customers will lead to an increase in AMP because the share of sales to higher-priced customers rises. The ultimate effect of this is that manufacturers will see erratic application of this rebate to their products, often due to forces completely out of their control. This is distinctly different from how these rebates function in the brand market, which sees steady price growth beyond the CPI threshold over time. This may lead to the following negative situations:

    - A generic drug manufacturer who holds their AMP constant would be subject to the penalty when CPI is negative (as has occurred five times in the past seven years[9]).
    - Because generic drug prices are significantly lower than brand drugs', a temporary and small (real) AMP increase would nonetheless expose them to the penalty. This would make continued production of low-cost and low-margin products, already challenged by supply disruptions, increasingly tenuous.
    - Even if a drug's AMP declined overall – as is the overwhelming trend in generic drugs – it would still face this penalty if it faced temporary increases due to changes in customer mix or supply disruptions.
    - As a result, the additional rebate amount will be very difficult to predict and there are multiple examples in which the rebate would be applied even though the Average Manufacturer Price (AMP) does not increase.

- As part of the Affordable Care Act, Congress already increased the ordinary Medicaid rebate on generic drugs from 11 percent to 13 percent. Before applying the far more complicated inflation-based rebate to generic drugs, it would be important to first fully understand the impact of the last generic drug rebate increase.

[9] *Bureau of Labor and Statistics, CPI*

Applying an inappropriate policy solution to a fundamentally different market without careful consideration threatens a legacy of savings from generic drugs, including $254 billion in health system savings in 2014alone. The total savings from generic drugs over the last 10 years was $1.68 trillion.

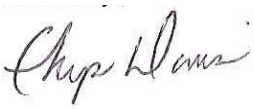
On an annual basis, the savings from generic drugs could fund the following programs for two years with possibly $50 billion left over:

- All drugs dispensed under the Medicare Part B benefit,
- all drugs dispensed under the Medicare Part D benefit,
- all drugs dispensed through Veterans Administration (VA) and TriCare programs,
- and the entirety of the Children's Health Insurance Program (CHIP).

GPhA feels strongly that this provision should be repealed in favor of alternative policies that enhance, rather than harm, patient access to affordable, quality generic medicines that benefit millions of Americans and control overall health spending.

We look forward to working with each of you to expand access to safe and effective generic medicines.

Sincerely,



Chester "Chip" Davis, Jr., J.D.
President and Chief Executive Officer

cc: The Honorable Sylvia Burwell
Secretary
Department of Health and Human Services

The Honorable Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services