Congress of the United States
Washington, DC 20515

October 19, 2015

The Honorable Gene L. Dodaro
Acting Comptroller General of the United States
U.S. Government Accountability Office
441 G Street, NW
Washington, DC 20548

Dear Mr. Dodaro:

We write today to request that the Government Accountability Office (GAO) undertake a study to examine the rising prices of prescription drugs. Recent price increases are preventing some patients from getting the drugs they need. These increases – some quite significant – merit further investigation to better understand what factors are driving these price spikes and their impact on federal spending.

Americans saw nationwide spending on drugs increase more than 12 percent last year, according to the Centers for Medicare and Medicaid Services. That increase was more than double the rise in overall medical costs.[1] Extreme prescription drug price increases have garnered national attention over the past year: Some drug manufacturers appear to be exploiting a monopoly (or near monopolies) on certain products by buying up existing drugs that do not have much competition – either in cases where a branded product is still under patent protection, but also in cases where a drug has been off-patent for decades and there is little or no competition – and raising prices aggressively. Here are several widely reported examples:

- Gilead Pharmaceuticals bought the rights to the Hepatitis C drug Sovaldi and began selling it at $1,000 per pill. Gilead's revenues doubled last year while state and federal government payers have reported they are unable afford this medication for the patients who need it.[2] Spending on specialty drugs increased more than 26 percent to $124 billion in 2014, driven in large part by the high cost of Hepatitis C treatments like Sovaldi.[3] Even at a discounted rate, the Department of Veterans Affairs asked Congress for an additional $1.3 billion to provide Sovaldi and other Hepatitis C drugs to patients this year.[4]

- Valeant Pharmaceuticals, which announced this week it received a subpoena from the U.S. Attorney's Offices in both Massachusetts and New York, raised the price of two drugs – Isuprel and Nitropress – by 525 and 212 percent respectively, immediately after the buying the drugs from Marathon Pharmaceuticals in February. Valeant is the only manufacturer of these drugs. These enormous increases come on the heels of nearly 400 percent increases last year by Marathon Pharmaceuticals, which raised their prices after acquiring them from Hospira in 2013.[5] Valeant has raised the price significantly on many other drugs in the last two years, including

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[1] *2014-2024 Projections of National Health Expenditures Data Released*, Centers for Medicare and Medicaid Services (July 28, 2015).
[2] *The True Cost of an Expensive Medication,* The Atlantic (Sept. 25, 2015).
[3] *Medicines Use and Spending Shifts: A Review of the Use of Medicines in the U.S. in 2014,* IMS Institute for Healthcare Informatics (Apr. 14, 2015).
[4] *VA, DoD Spend More than $450M on Costly Hepatitis Drug*, USA Today (Jan. 28, 2015).
[5] *Pharmaceutical Companies Buy Rivals' Drugs, Then Jack Up the Prices*, Wall Street Journal (Apr. 26, 2015).

- Glumetza ($896 to $10,020 for 90 tablets), Syprine ($1,395 to $21,267 for 100 capsules), and Cuprimine ($888 to $26,189 for 100 capsules).[6]

- When GlaxoSmithKline sold the marketing rights for albendazole, an antiparasitic, to Amedra Pharmaceuticals in 2010 and a competitor left the market in 2011, the price rose from $5.92 to $119.58 per typical daily dose.[7]

- Last month, Turing Pharmaceuticals raised the price on a 62-year-old antiparasitic drug, Daraprim, from $13.50 a tablet to $750 a tablet, immediately after acquiring the rights to the drug.[8]

As strong supporters of access to generic pharmaceuticals, we know from the Congressional Budget Office and GAO that generic drugs provide tremendous cost savings to our health care system and to the federal government.[9] By 2013, generics accounted for 29 percent of pharmaceutical spending and 86 percent of drugs dispensed in the United States.[10] However, higher generic drug prices increase the costs to American taxpayers, and prevent consumers from accessing the drugs they need. At a November 20, 2014 hearing before the Senate Committee on Health, Education, Labor, and Pensions, Subcommittee on Primary Health and Aging, the Committee received testimony from consumers, experts, and pharmacists on these price spikes and their impact on patients.

According to a Congressional Research Service (CRS) analysis of National Average Drug Acquisition Cost (NADAC) data, half of all generic NADAC drug groupings went up in price between July 2, 2013, and June 30, 2014. During this same time period, nearly 10 percent of drugs more than doubled in price. See Table 1.

Table 1. Summary of Generic Drug Average Acquisition Cost Changes
Between the Weeks of July 2, 2013 and June 30, 2014

Percentage Changes in National Average Drug Acquisition Cost	Number of National Drug Codes	Number of NADAC Generic Drug Groupings	Percent of Total NADAC Generic Drug Groupings
-25.0% to -90+%	559	77	2.9%
-10.0% to -24.9%	2,411	346	12.9%
-5.0% to -9.9%	2,189	367	13.7%
-0.1% to -4.9%	3,059	531	19.9%
0%	12	7	0.3%
0.1% to 4.9%	2,462	421	15.8%
5.0% to 9.9%	967	210	7.9%
10.0% to 24.9%	830	232	8.7%
25.0% to 99.9%	816	230	8.6%
100% to 17,000+%	1,215	251	9.4%
Total	14,520	2,672	100.0%

Source: CRS analysis of CMS NADAC data from surveys for the weeks ending July 2, 2013 and June 25, 2014. Numbers may not sum due to rounding.

[6] *Valeant's Drug Price Strategy Enriches It, but Infuriates Patients and Lawmakers,* New York Times (Oct. 4, 2015).
[7] *High-Cost Generic Drugs – Implications for Patients and Policymakers,* New England Journal of Medicine (Nov. 13, 2014).
[8] *Drug Goes From $13.50 a Tablet to $750, Overnight,* New York Times (Sept. 20, 2015).
[9] Congressional Budget Office, *Competition and the Cost of Medicare's Prescription Drug Program* (July 2014); Government Accountability Office, *Drug Pricing: Research on Savings from Generic Drug Use* (Jan. 31, 2012) (GAO-12-371R).
[10] IMS Institute for Healthcare Informatics, *Medicine Use and Shifting Costs of Healthcare* (Apr. 2014).

Also see, for example, the effects of these price increases on Medicaid fee-for-service (FFS) drug expenditures for just six selected drugs. Despite a decline in the number of prescriptions filled, spending on these drugs increased significantly.

Table 3. Estimated Medicaid FFS Drug Expenditures for Selected Generic Drugs

July 1, 2012 to June 30, 2013 and July 1, 2013 to June 30, 2014

Selected Drugs	07/01/2012-06/30/2013		07/01/2013-06/30/2014		Percentage Change	
	Number of Prescriptions	Medicaid Paid[a]	Number of Prescriptions	Medicaid Paid[a]	Number of Prescriptions	Medicaid Paid[a]
Albuterol Sulfate 2 MG Tablet	4,255	$162,700	3,300	$823,953	-22.44%	406.4%
Doxycycline Hyclate 100 MG Capsule	436,778	$7,331,824	272,456	$16,225,250	-37.62%	121.3%
Divalproex Sodium ER 500 MG Tablet	604,801	$24,048,150	463,085	$80,131,865	-23.43%	233.2%
Pravastatin Sodium 10 MG Tablet	63,380	$491,351	76,759	$996,004	21.1%	102.7%
Benazepril-Hydrochlorothiazide 20-25 MG Tablet	12,702	$177,912	10,866	$328,323	-14.4%	84.5%
Digoxin 250 MCG Tablet	75,128	$594,952	63,303	$1,130,834	-15.7%	90.1%
Total for these Drugs	1,197,044	$32,806,890	889,769	$99,636,229	-25.7%	203.7%

Source: CRS analysis of CMS Medicaid drug utilization data. Medicaid data are for fee-for-service (FFS) prescriptions only and are based on data reported by states and DC. The Medicaid paid amount in Table 3 includes both state and federal expenditures. No attempt was made to verify these data or to determine if all states submitted data.

Notes: a. Before all Medicaid rebates.

We are writing to request that GAO conduct a study to examine the causes of rising drug prices. We ask that GAO address the following questions and issues:

1. Provide an overview of the pharmaceutical industry, including any estimates of its size and scope, profitability, research and development (R&D) expenditures, and market concentration. In particular, please address the question of the extent to which the industry has experienced consolidation over the past decade, and how these dynamics have affected competition, pricing, and research outlays.

2. Brand name and generic pharmaceutical prices are outrageously high. One possible cause is a wave of mergers among companies that make these vital medicines. Antitrust agencies such as the Federal Trade Commission and the Department of Justice are not supposed to let this happen.[11] They have a mandate to ensure that mergers across most industries do not reduce competition and increase prices for consumers. Yet, there seems to be a policy failure in antitrust oversight when it comes to mergers in the pharmaceutical and generic pharmaceutical industries. Please look at a reasonable sample of mergers and other similar transactions in this space and determine whether those mergers led to price increases. In addition, please examine whether antitrust and other agencies' predictions – as well as submitted industry predictions – about prices and changes in R&D spending in the pharmaceutical and generic pharmaceutical industry were accurate.

3. Within the generic pharmaceutical industry, please examine all potential causes of price increases, including those related to the supply chain, prices and availability of raw materials,

[11] Kwoka, John, *Does Merger Control Work? A Retrospective on U.S. Enforcement Actions and Merger Outcomes,* Antitrust Law Journal (Apr. 4, 2012).

anti-competitive business practices, market concentration, regulatory factors, and any other issues that GAO identifies as relevant. In particular, please address the question of the extent to which the industry has experienced consolidation over the past decade, and how these dynamics have affected competition and pricing.

4. Analyze the market effects of restricted distribution arrangements involving brand name medicines, implemented either as part of a Risk Evaluation and Mitigation Strategy approved by the Food and Drug Administration (21 U.S.C. § 355-1) or voluntarily through a contractual or other agreement. In particular, analyze the effects of such restricted distribution arrangements on the ability of generic pharmaceutical companies to access brand name medicine supplies for the purpose of demonstrating bioequivalence in Abbreviated New Drug Applications.

5. Provide case studies from state Medicaid programs showing the effects of significant prescription drug price increases on Medicaid expenditures. Include an evaluation of the time period over which these price increases were sustained, an examination of the reasons behind the price increases, and an analysis of whether the prices returned to previous levels upon resolution of the issue leading to the price increase.

Should you have any questions concerning this request, please contact Sophie Kasimow on Senator Sanders' staff at (202) 224-5480 or Kelly Christl on Congressman Cummings' staff at (202) 225-5051.

Sincerely,

Senator Bernard Sanders
Ranking Member
Subcommittee on Primary Health
and Retirement Security
Committee on Health, Education, Labor
and Pensions
United States Senate

Congressman Elijah E. Cummings
Ranking Member
Committee on Oversight and Government
Reform
United States House of Representatives