July 25, 2017

Hon. Tom Marino
Chair, Regulatory Reform,
Commercial & Antitrust Law Subcommittee
House Judiciary Committee
U.S. House of Representatives
2138 Rayburn House Office Building
Washington, D.C. 20515

Hon. David Cicilline
Ranking Member, Regulatory Reform,
Commercial & Antitrust Law Subcommittee
House Judiciary Committee
U.S. House of Representatives
2138 Rayburn House Office Building
Washington, D.C. 20515

Dear Chairman Marino and Ranking Member Cicilline:

On behalf of the Coalition to Reduce Spending, I am writing in support of the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act (H.R. 2212), bipartisan legislation to increase competition and patient access to safe and affordable generic and biosimilar medicines. We appreciate your willingness to hold a hearing on this important bill and urge the Committee to mark-up the bill and move it to the House floor promptly.

As founder and president of a nonpartisan organization dedicated to reducing spending and debt, I represent the Americans nationwide who are concerned about rising national debt and growing dysfunction in Washington. We are encouraged to see efforts to reform one aspect of one of the fastest-growing parts of the federal budget.

In 1960, healthcare costs were just 5 percent of Gross Domestic Product. By 2015, they were nearly 18 percent and on track to keep growing. Prescription drug costs were 10% of total healthcare spending, and in recent years, their growth rate has outpaced that of all other services. When costs rise, the federal government and taxpayers bear the largest burden.[1]

As you know, the Food and Drug Administration's Risk Evaluation and Mitigation Strategies (REMS) were created to ensure consistency in drug manufacturing and minimize potential risks to patient safety. However, in recent years, REMS increasingly have been abused to make it more difficult for generic and biosimilar manufacturers to enter the marketplace.

More than 150 complaints have been sent to the FDA, and recent research estimates the potential scope of the current brand revenue of the products affected by this loophole at $22 billion.[2] This problem is growing, yet the FDA does not currently have the ability to prevent REMS abuse. Consequently, Congressional action is necessary.

[1] Centers for Medicare and Medicaid Services. "NHE Fact Sheet," June 2017.
[2] Matrix Global Advisors, Alex Brill, "REMS and Restricted Distribution Programs: An Estimate of the Market," June 2017.

While some may suggest that these legislative solutions would encourage excessive litigation against brand-name manufacturers, the reality is that disputes of all kinds are already being litigated through the court system and adding clarity to FDA's rules would reduce misunderstandings, not increase it. These narrowly tailored proposals would give an affirmative defense for brand manufacturers against frivolous claims, while ensuring that REMS functions as intended – to protect patients, not to defend anyone's bottom line. And of course, less litigation would ultimately mean lower drug costs for consumers – and the U.S. government.

Research shows that most Americans want Congress to spend less and find ways to cut waste. A vast majority of Americans (87%) favor "making it easier for generic drugs to come to market in order to increase competition and reduce costs."[3] There are good reasons for both of these beliefs.

As the national debt hovers around $20 trillion, critical national priorities are endangered, yet deep dysfunction continues to make serious reform difficult. In this environment, any opportunity to cut government spending or reform its finances is welcome, and CREATES is one such opportunity. A 2013 analysis, for instance, found overall savings from allowing just 11 biosimilars to enter the market would exceed $250 billion over the decade.[4] While there is a range of estimates, nearly all suggest savings – and some have predicted government cost savings as high as $71 billion.[5] Now more than ever, this potential for reform cannot be overlooked.

Thank you for the consideration of our views. Please do not hesitate to contact me at (202) 503-6551 or Jonathan@ReduceSpending.org.

Sincerely,

Jonathan Bydlak
President

[3] Kaiser Family Foundation, "Poll: Majorities of Democrats, Republicans and Independents Support Actions to Lower Drug Costs," May 2017.
[4] Frazee, Dr. Sharon Glave, et al. "Ten-Year Potential Savings from Biosimilars in California," September 2013.
[5] Mulcahy, Andrew. RAND. "The Cost Savings Potential of Biosimilar Drugs in the United States," 2014.