PUBLIC SECTOR HEALTHCARE ROUNDTABLE

July 27, 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 Public Sector HealthCare Roundtable I am writing to you today 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. I commend you for holding a hearing on this important bill and urge the Committee to mark-up the bill and move it to the House floor promptly.

The Public Sector HealthCare Roundtable is a non-profit, non-partisan coalition of public sector purchasers from across the U.S. including states, counties, and municipalities that collectively spend over $14 billion annually on health care benefits to provide coverage for millions of employees, retirees, and their dependents. Access to safe, effective and affordable pharmaceutical products -- and especially both brand and generic biologics -- is a longstanding high-priority for the Roundtable and its members.

Today, certain brand pharmaceutical companies are currently preventing competition by blocking generic and biosimilar drug manufacturers' ability to purchase samples, which are used to conduct the bioequivalent testing necessary to bring safe and affordable generic and biosimilar medicines to market at the earliest possible date. The Food and Drug Administration (FDA) has stated that this anti-competitive practice – known as Risk Evaluation and Mitigation Strategy (REMS) and non-REMS restricted access abuse – is "a problem" that "delays the availability of generics."[1]

More than 150 complaints have been sent to the FDA and a significant majority of these brand drug products are quite expensive, costing patients thousands of dollars per month. 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 and patient access to safe and affordable generic and biosimilar medication is being delayed.

Administration

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[1] Food & Drug Administration (FDA), Dr. Janet Woodcock, Congressional Testimony before House Committee on Oversight & Investigations, March 22, 2017.
[2] Matrix Global Advisors, Alex Brill, "REMS and Restricted Distribution Programs: An Estimate of the Market," June 2017.

Unfortunately, the FDA does not have the authority to prevent the abuse of REMS and restricted access programs. REMS put in place important safety protocols, but are explicitly prohibited from being used to delay or prevent generic competition. It should be noted that generic drug developers are required to adhere to safe handling and other structures that protect patient safety, and this is done every time brand companies permit the sale of samples for generic drug development.

To ensure that generic drug developers are not prevented by a small handful of brand companies from obtaining samples necessary to bring new accessible generic and biosimilar drugs to patients and payors, congressional action is necessary. The bipartisan CREATES Act (H.R. 2212) would provide a safe, efficient and targeted pathway to end these abusive, anti-competitive tactics. The FDA is well-known for its "gold standard" in protecting the safety of patients and in the Agency's review of the CREATES Act has stated that current FDA guidance on the provision of samples protects patients.

With nearly nine out of ten Americans (87%) in favor of "making it easier for generic drugs to come to marker in order to increase competition and reduce costs"[3] and over 18 health care stakeholders calling for congressional action to provide "generic and biosimilar manufacturers a clear and efficient pathway to combat these bad actors," support for the bipartisan CREATES Act (H.R. 2212) is broad and well-founded. Thank you for holding this important hearing and I look forward to watching the bill's progress in your Committee.

Thank you for the consideration of our views. Please do not hesitate to contact the Roundtable Senior Policy Advisor, Andrew MacPherson, at 202-909-2870 or andrew@healthsperien.com.

Sincerely,

Thomas R. Lussier

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[3] Kaiser Family Foundation, "Poll: Majorities of Democrats, Republicans and Independents Support Actions to Lower Drug Costs," May 2017.