Johnson Matthey
Inspiring science, enhancing life

Johnson Matthey Inc.
435 Devon Park Drive Ste 600
Wayne, PA 19087
T +1 610 971 3043

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

July 11, 2017 **Subject: CREATES Act (H.R. 2212)**

Dear Chairman Marino and Ranking Member Cicilline:

On behalf of Johnson Matthey and our 2,726 US employees, 1,250 of whom live and work in the Commonwealth of Pennsylvania, 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. We 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.

In business for over 200 years, Johnson Matthey is a global leader in sustainable technologies with around 13,00 people worldwide in over 30 countries, including the United States. Through our Health Sector, we strive to bring cost effective, niche treatments to the market, providing custom pharmaceutical solutions for drug development through commercial manufacturing, and an extensive range of Active Pharmaceutical Ingredients for both the brand and generic markets.

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] Johnson Matthey has witnessed this delay first-hand.

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.

[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 even 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 we 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 me should you or your staff have any questions.

Sincerely,

Ross J. Oehler

Assistant General Counsel

Johnson Matthey
Inspiring science, enhancing life

Johnson Matthey Inc.

435 Devon Park Drive, Suite 600
Wayne, PA 19087-1988
T +1 610-971-3043
M +1 610-389-1196
Ross.Oehler@jmusa.com

www.matthey.com
Follow us on: Twitter | LinkedIn | Instagram

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