APOTEX

Innovating for
patient affordability

July 27, 2017

Honorable 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

Honorable 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:

I am writing on behalf of Apotex and our nearly 500 US-based employees to thank you for your continued commitment to ending anticompetitive practices in the pharmaceutical marketplace that are obstructing timely access for the public to quality, affordable generic medicines. We commend you for holding today's hearing and your efforts to curb the use of Risk Evaluation and Mitigation (REMS) and other restricted access programs by brand drug companies to delay generic competition. Apotex strongly supports the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act (H.R. 2212), bipartisan legislation that will lower drug costs for all Americans. We urge that you expeditiously mark up the bill and move it to the House floor for consideration.

To enhance patient safety, in 2007 Congress authorized the FDA to require REMS for drugs having a high potential of misuse or serious side effects. These postmarketing surveillance programs are intended to assure that a drug's benefits outweigh its risks. Regrettably, soon after the law took effect, brand drug companies began exploiting it to impede competition and prolong monopolies by blocking the sale of brand product samples generic competitors require for development testing. This practice, which has grown increasingly worse since the law's initial enactment, is also being employed to obstruct access to products not subject to REMS requirements. A recent study of this abusive tactic found that "the restricted access drug segment comprises 74 drugs with total sales of $22.7 billion in 2016."[1]

Apotex is among the many generic and biosimilar companies who have had the development and approval of products delayed as a result of this abusive practice. The FDA reported to Congress earlier this year that it is has received some 150 complaints from generic drug

[1] Matrix Global Advisors, Alex Brill, "REMS and Restricted Distribution Programs: An Estimate of the Market," June 2017.

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companies across the industry that were unable to obtain needed drug samples.[2] Unfortunately, FDA does not have the authority to stop the gaming of this patient safety law.

The CREATES Act will combat this manipulative practice by establishing an efficient, tailored path for generic drug and biosimilar manufacturers to acquire the samples needed for development purposes. In so doing, it will correct an exploitation of the generic and biosimilar approval processes that is undermining the ability of those regimes to function as Congress intended. Indeed, as the broad range of stakeholders calling for remedial action at FDA's July 18 public meeting focusing on the administration of the Hatch-Waxman Act illustrated, the use of REMS and restricted access programs to delay generic competition disrupts the balance between access and innovation in the pharmaceutical market established by Congress to serve the best interests of patients. Accordingly, we urge you to move expeditiously following today's hearing to mark up the CREATES Act and bring it to the House floor for consideration.

Again, thank you for holding this important hearing and your commitment to ensuring patients have timely access to quality, affordable generic medicines. Please do not hesitate to contact me at 301-654-4964 or sgiuli@apotex.com if Apotex can be of any assistance at all.

Sincerely,

Steve Giuli

Steve Giuli
Vice President of Government Affairs & Trade Relations

[2] Food & Drug Administration (FDA), Dr. Janet Woodcock, Congressional Testimony before House Committee on Oversight & Investigations, March 22, 2017.