



July 20, 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:

As a leading generic pharmaceutical developer in the United States and a provider of more affordable medicines to American patients, I write with much appreciation for the July 27 hearing you are holding on H.R. 2212, the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act.

At the outset of generic product development, Amneal must use brand samples to conduct FDA-required bioequivalence testing. These samples are used solely for the purpose of demonstrating to the FDA that the generic medicine is therapeutically equivalent to the brand referenced drug. Without access to brand samples, product development cannot commence and patients are denied timely access to more affordable generic medicines. Simply put- no samples, no generics.

A prevalent strategy by brand drug companies to forestall generic drug market entry is using the Food and Drug Administration Risk Evaluation and Mitigation Strategy (REMS) program as a regulatory obstacle for generic developers seeking to obtain brand drug samples. Amneal has experienced first-hand the consequences of this anti-competitive misuse of the REMS program and both the FDA and the Federal Trade Commission have acknowledged the improper use of REMS to impede generic competition

Congressional action is needed to provide generic developers with a safe, efficient and targeted pathway to secure samples. Amneal believes the CREATES Act will facilitate drug sample procurement, greater generic market competition and more affordable pricing options for American patients.

Amneal Pharmaceuticals urges the committee to mark-up H.R. 2212 and move it to the House floor promptly. Thank you for considering the views of Amneal and if you or your staff have a questions or need additional information, please feel free to contact me at bkaufman@amneal.com or (908) 947-3139.

Sincerely,

A handwritten signature in black ink, appearing to read "Beth Zelnick Kaufman", written over a horizontal line.

Beth Zelnick Kaufman
Vice President, Legal Affairs

cc: The Honorable Jerry Nadler
The Honorable Hakeem Jeffries
The Honorable Brad Schneider