



June 27, 2019

Sen. Lindsey Graham  
Chairman  
Senate Committee on the Judiciary  
224 Dirksen Senate Office Building  
Washington, D.C. 20515

Sen. Diane Feinstein  
Ranking Member  
Senate Committee on the Judiciary  
224 Dirksen Senate Office Building  
Washington, D.C. 20515

Dear Chairman Graham and Ranking Member Feinstein:

On behalf of the Association for Accessible Medicines (AAM) and its member companies, we are writing to offer our industry's full support for your Committee's decision to mark-up the Preserving Access to Cost Effective Drugs (PACED Act) of 2019 (S. 440). The PACED Act is a straightforward, common-sense solution to ensure patient access to more affordable, FDA-approved generics and biosimilars. We encourage your Committee to approve this important legislation and send it to the full Senate to ensure prompt passage. The PACED Act will address real abuses of the patent system and help lower the price of medicines.

Brand pharmaceutical companies are finding new, innovative ways to avoid competition from generic and biosimilar medicines, extend their government-provided monopolies and keep patients paying high drug prices. Look no further than Allergan.

In a first-of-its-kind maneuver, Allergan sold its patents on Restasis – an eye medication with \$1.5 billion in annual revenue – to the St. Regis Mohawk Tribe for a one-time payment of nearly \$14 million and annual royalties of \$15 million. In exchange, the St. Regis Mohawk Tribe immediately filed a motion to dismiss, based on a claim of tribal sovereign immunity that would negate the U.S. Patent Office's pending review of the Restasis patents.

Concerned about the likelihood of the U.S. Patent Office determining that the Restasis patents were invalid, Allergan engaged in a blatant attempt – and in what a federal judge later called a “sham transaction” – to circumvent a sensible law passed by Congress on a bipartisan basis only a few years ago. Patient groups, health care providers and even other pharmaceutical CEOs openly criticized Allergan's patent “shenanigans.” And one independent estimate pegged the cost to patients at \$10.7 billion as a result of this deal.

Now Senators Tom Cotton, Joni Ernst, David Perdue and Pat Toomey are stepping in to stop this kind of abuse of the patent system, disregard of congressional intent and profiteering from patients. The PACED Act adheres to a simple premise: those who choose to participate in the patent system must play by its rules.

Congress did not intend for the patent system to be abused in this manner. The PACED Act would prohibit the rental of a tribe's sovereign immunity by Allergan or any other company. This problem isn't limited to just one blockbuster drug. If Congress doesn't respond and Allergan's business deal is upheld in the courts, these types of transactions could easily be replicated across the brand pharmaceutical industry, resulting in higher drug prices for everyone.

Allergan's patent "gamesmanship" has already thwarted patient access to generics since the initial Restasis patents expired in 2014. With these recent legal maneuvers, Allergan has successfully delayed generic competition until 2020 even though the courts repeatedly ruled against this transaction. Unfortunately, while Allergan uses every legal tool in its arsenal to extend its monopoly protections, the company simultaneously increases the price of Restasis for millions of patients.

The PACED Act is a straightforward, common-sense solution to ensure patient access to more affordable, FDA-approved generics and biosimilars. We welcome the Committee's action on this important bill and look forward to its enactment.

Sincerely,

A handwritten signature in black ink that reads "Chester Davis Jr." in a cursive style.

Chester "Chip" Davis, Jr.