United States Senate
WASHINGTON, DC 20510

July 20, 2017

The Honorable Scott Gottlieb, M.D.
Commissioner
U.S. Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket # FDA-2017-N-3615 for "Administering the Hatch-Waxman Amendments: Ensuring a Balance Between Innovation and Access; Public Meeting; Request for Comments"

Dear Commissioner Gottlieb:

Thank you for holding the public meeting on July 18, 2017, "Administering the Hatch-Waxman Amendments: Ensuring a Balance Between Innovation and Access," to ensure the balance between encouraging innovation in drug development and accelerating the availability to the public of lower cost alternatives. We appreciate your leadership and efforts to raise awareness about how the FDA's rules are being used to decrease competition and delay the entry of generic drugs into the market.

Since enactment of Hatch-Waxman, patients have benefited from increased access to safe, affordable, and high quality generic medicines. However, the critical balance between innovation and access is jeopardized by current abuses and manipulation of the regulatory process. As you recognized in your recent testimony before the Senate Appropriations Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies, "The bottom line is that there is no question there are places where companies do take advantage of rules meant for one purpose as a way to gain commercial advantage."[1]

We agree with your concern that some companies are manipulating the Risk Evaluation Mitigation Strategy (REMS) programs to delay generic competition. To alleviate this problem, we have introduced the CREATES Act (S.794), which addresses two abuses of the REMS program while maintaining current patient safety standards and helping to lower prescription drug costs. The REMS issue is well understood, and the CREATES Act provides a simple and effective solution.

Certain branded companies are currently preventing generic competitors from obtaining branded samples. Without access to these branded samples, a generic company cannot conduct the testing necessary to receive FDA approval, delaying lower-cost competition that would benefit consumers. Just last year, the FDA reported that it had received more than 150 inquiries from

[1] https://www.appropriations.senate.gov/hearings/review-of-the-fy2018-food-and-drug-administration-budget-request

generic drug companies unable to obtain samples needed for bioequivalence testing.[2] The FDA also noted, "Many of these brand drug products are quite expensive. A significant majority of these drug products are listed online at a retail price of over $600 per patient per month, and many are in the range of thousands of dollars per patient per month."[3]

Some companies argue that certain REMS, which limit how a prescription drug is distributed (known as Elements to Assure Safe Use, or "ETASU") prevent the sale of the product to a generic company. The FDA rightly rejected this justification. The purpose of an ETASU is to protect patients, not to prevent potential competitors from obtaining needed samples.

The CREATES Act would address this issue by creating a narrow remedy that generic companies could use to quickly obtain samples when a branded company abuses the regulatory process in this manner. In the case of drugs subject to limited distribution requirements, our legislation maintains current safety protections for bioequivalence testing, which the FDA has said are adequate.

Under current law, if a REMS requires an ETASU, there is a presumption that a generic manufacturer and the brand should use the same REMS, which is known as a single, shared REMS. The FDA may waive the requirement and approve a separate system for the generic product if the burden of creating a single, shared system outweighs the benefit of a separate system. As a practical matter, until the branded and generic companies agree to a single, shared system or the FDA waives that requirement, the generic company cannot receive approval. Meanwhile, the branded company, under the previously approved REMS, continues to maintain a monopoly and sell its product without facing generic competition.

The longer branded companies delay reaching an agreement on single, shared systems, the longer they avoid competition and deny consumers cost-saving alternatives. In nearly a decade since Congress created this system, to our knowledge, only one branded company has reached agreement on a single, shared REMS prior to the generic company receiving FDA approval. The FDA has approved five other single, shared REMS, but in those cases, the REMS was required after both the branded and generic company were approved and on the market. This pattern suggests that when branded companies are not benefiting by extending negotiations, it is easier to reach agreement on a single, shared REMS. In addition, there are now 11 single, shared REMS systems in negotiations, "many of which involve the costliest medications to patients and to Medicare spending as a whole." In all but one of these negotiations, the parties have missed at least one of the milestones set by the FDA. In January, the FDA waived the single, shared REMS requirement for a product after four years of failed negotiations.[4]

The CREATES Act provides a narrow and simple solution to this second abuse. It would eliminate the presumption of a single, shared REMS, and the associated unintended incentives to delay competition. Instead, the FDA would be authorized to either approve a single system for the generic product that meets the same, safety requirements as the branded company's system or

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[2] See Letter from Dayle Cristinzio, Associate Commissioner for Legislation, to Senator Patrick Leahy (December 22, 2016)

[3] *Id.*

[4] https://www.law360.com/articles/940982/fda-may-push-boundaries-to-speed-rems-negotiations

require a single, shared REMS when necessary. This approach does not change the safety requirements for generic drugs subject to a REMS.

One of the regulatory issues on which we encourage you to take action is with respect to whether the FDA can waive the requirement for a single, shared REMS "more readily" than it has in the past. In particular, we urge you to consider implementing a framework in which the FDA would waive a single, shared REMS if, after a good faith effort or a reasonable amount of time, the generic company has submitted a separate proposal that satisfies the legal requirements for a REMS.

While we look forward to hearing more from you about what regulatory actions you believe the FDA can take to address strategies that prevent generics from obtaining samples needed for required regulatory testing and abuses in the REMS program, we believe Congressional action on the CREATES Act is necessary and an essential part of the solution to ending these abuses. We would welcome the opportunity to work with you on this legislative solution.

Thank you again for your attention to these issues. We look forward to working with you to promote safe, effective, and affordable drug prices by fostering greater competition.

Sincerely,

PATRICK LEAHY
United States Senator

CHARLES E. GRASSLEY
United States Senator

AMY KLOBUCHAR
United States Senator

MIKE LEE
United States Senator