September 23, 2019

The Honorable Lamar Alexander
Chairman
Senate HELP Committee
428 Dirksen Senate Office Building
Washington, D.C. 20510

The Honorable Patty Murray
Ranking Member
Senate HELP Committee
154 Russell Senate Office Building
Washington, D.C. 20510

Dear Chairman Alexander and Ranking Member Murray,

Thank you for your leadership in advancing bipartisan drug pricing legislation, the Lower Health Care Costs Act (S. 1895), through the HELP Committee. Our respective organizations support your efforts to lower prescription drug prices for consumers, taxpayers, and the millions of patients that many of us represent by enhancing generic and biosimilar competition.

In 1984, the passage of the *Drug Price Competition and Patent Term Restoration Act* (Hatch-Waxman Act) established an approval pathway for generic drugs in the United States. The entry of generic and biosimilar medicines into the market can and does drive down prices for prescription drugs. These lower prices benefit patients, consumers, and the U.S. health care system.

Brand-name drug companies often attempt to prevent competition by creating patent thickets: the filing of dozens of new patents that extend the monopoly life of their products for decades after initial approval. These patents can be successfully challenged and defeated in court by generic manufacturers, paving the way for a generic medication to come to market and give patients the option of a lower-cost alternative. However, patent litigation is extremely expensive and time-consuming; therefore Hatch-Waxman Act created the 180-day market exclusivity as an incentive for generic manufacturers to pursue this patent litigation. This incentive has resulted in hundreds of challenges to brand-name drug patents. These challenges have provided an enormous benefit to patients and our health system, saving almost $2 trillion over the last decade.[1]

One of the central goals of the Lower Health Care Costs Act is to increase competition and patient access to lower cost medicines. Section 205 of the legislation attempts to address the Food and Drug Administration's (FDA) concerns about the "parking" of generic applications. Our organizations believe steps should be taken to ensure generic manufacturers seek approval and launch new medications into the market as soon as possible after approval. However, we are concerned that, as written, Section 205 may have unintended consequences that may undercut the goal of the 180-day exclusivity period. Our concern is that this may actually result in fewer generics coming to market.

As currently written under Section 205, a first-to-file generic drug manufacturer may lose the 180-day incentive due to several common scenarios and *through no fault of its own.* These scenarios were identified by former FDA Commissioner Scott Gottlieb, who urged Congress to fix the issue.[2] As a result, as written, Section 205 would severely diminish the incentive for generic manufacturers to

[1] https://www.optum.com/resources/library/2018-generics.html.

[2] Scott Gottlieb, The HELP Committee's Fix For 180-Day Generic Marketing Exclusivity: Does It Solve The Problem?, *available at* https://www.healthaffairs.org/do/10.1377/hblog20190529.223594/full/ ("Any provision should protect generic companies from forfeiting the exclusivity if they're actively seeking final approval"); Donna Haseley, Gottlieb: Senate HELP's 180-Day Generic Exclusivity Fix Falls Short, Inside Health Policy (June 7, 2019).

challenge patents, even if they believe a patent to be invalid. As prescription drug prices in the U.S. continue to rise, we believe that Congress should prioritize ensuring that generic manufacturers have proper incentives to bring lower cost medications to the market.

Our organizations urge you to amend Section 205 and ensure that a **first-to-file generic manufacturer, who is "actively seeking FDA approval" will not lose the 180-day incentive they need to get these products on the market and in the hands of patients.** The "actively seeking FDA approval" standard, as the FDA asserted in Mylan v. Sebelius (2012), will help ensure that generic manufacturers who are diligently seeking final approval in good faith will not be unfairly penalized.[3] It will also allow the FDA to address quality and manufacturing issues by promptly triggering the 180-day exclusivity period if an application contains a false or misleading statement of fact. Further, it will result in faster drug approvals by requiring generic manufacturers to expeditiously seek final approval of tentatively-approved applications. We believe that the "actively seeking FDA approval" standard will achieve the same goals as Section 205 without undercutting the 180-day market exclusivity provided by the Hatch Waxman Act and result in bring generic drugs to patients sooner.

We thank you for your role in ensuring the passage of the Lowering Health Care Cost Act out of Committee and our organizations share your goal of lowering the costs of prescription drugs to give patients greater access to the medicines they need. We look forward to working with you on this important legislation.

Sincerely,

Allergy & Asthma Network
American Consumer Institute
Black Women's Health Imperative
Center for Freedom and Prosperity
Citizen Outreach
Coalition to Reduce Spending
Consumer Action
Global Healthy Living Foundation
Hematology/Oncology Pharmacy Association
Innovation Defense Foundation
Marti Nelson Cancer Foundation
Mended Hearts
NAACP
National Black Chamber of Commerce
National Consumers League
National Multiple Sclerosis Society
Spina Bifida Association

[3] Mylan Pharmaceuticals, Inc. v. Sebelius, 856 F. Supp. 2d 196 - Dist. Court, Dist. of Columbia 2012. Available at: https://bit.ly/2lBObEI.