PATIENTS RISING NOW

May 12, 2022

The Honorable Patty Murray
United States Senate
428 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Richard Burr
United States Senate
428 Dirksen Senate Office Building
Washington, DC 20510

Dear Chair Murray and Ranking Member Burr:

We appreciate the work of the Senate Committee on Health, Education, Labor, and Pensions (HELP) in reauthorizing the Food and Drug Administration's (FDA) user fee programs for generic drugs (GDUFA). The improvements in GDUFA III will speed patient access to safe, effective and more affordable generic medicines, especially complex generics. These improvements are real and measurable and worthy of the Committee's support and Congress' swift ratification.

Formed in 2015, Patients Rising has developed a significant following of over 110,000 patients and caregivers and has guided them on their journeys to advocate for themselves and their loved ones to get the care and treatments they need to live a fulfilling life. As a patient advocacy organization, we support reforms and legislation aimed at advancing patient access to affordable, quality healthcare – including low-cost generic medicines. For this reason, we write to raise serious concerns regarding ***The Expanding Access to Low Cost Generics Act*** **(S. 2910) and similar proposals contained in the Biden Administration's Fiscal Year 2023 Budget Request.**

We believe that diminishing or eliminating the Drug Price Competition and Patent Term Restoration Act's (Hatch-Waxman) 180-day exclusivity incentive for generic manufacturers would significantly and negatively impact patient access to critical low-cost generic medicines. For 38 years, the Hatch-Waxman Act has sped patient access to generic drugs by incentivizing generic drug manufacturers to undertake the risky and intensive work of challenging brand-name drug patents so they could bring a generic medicine to market earlier. By providing a 180-day market exclusivity period for the first marketed generic, Hatch-Waxman has created a pharmaceutical market that is the envy of the world; before the Hatch-Waxman Act, only 19 percent of prescriptions were filled with a generic, now 90 percent of all prescriptions are. This incentive – the only one available to generic developers – is the engine that has catalyzed this tremendous success.

S.2910 and proposals like it directly undermine this 180-day exclusivity incentive. 180-day exclusivity creates an essential incentive for generic drug development, and without it, generics developers face potentially insurmountable obstacles to challenging weak brand patents and navigating the laborious pathway to FDA approval. Without this incentive, drugs would remain on brand patent for longer periods—delaying generic drug access to patients and the healthcare system, perhaps indefinitely. Such policy outcomes are wholly inconsistent with the policy improvements agreed to in GDUFA III. Don't try to fix that which isn't broken.

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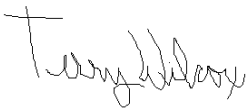
We urge you to reject S.2910 and similar proposals' misguided approach to Hatch-Waxman's 180-day exclusivity incentive and vote no on any legislation before the Senate that includes this policy change.

Sincerely,



Terry Wilcox
Executive Director

cc: Honorable Tina Smith; Honorable Mike Braun