



July 26, 2019

The Honorable Ted Cruz
127A Russell Senate Office Building
Washington D.C. 20510

Dear Senator Cruz:

On behalf of National Taxpayers Union, I write to thank you for introducing S. 2161, the Reciprocity Ensures Streamlined Use of Lifesaving Treatments (RESULT) Act of 2019. This legislation will lower regulatory barriers for bringing drugs, biologics and medical devices to market in the U.S., promote competition, and expand patient options, without compromising the free-market structure that supports innovative products.

As Congress grapples with rising health care costs, we have argued that the FDA's drug approval process is too long and cumbersome. As NTU's Pete Sepp wrote in an Issue Brief published in December:

“[T]he FDA's current approach is outdated and fails to meet the needs of a modern and increasingly complex health care system. Lengthy and costly regulations can cause delays to innovative breakthroughs that would enhance public health.”

...“Faster approval of safe drugs can increase innovation, and by approving drugs more quickly, it can decrease costs associated with research and development.”¹

The RESULT Act would be a strong first step to reforming the FDA's outdated approach, by providing an expedited, reciprocal approval process for drugs, biologics, or medical devices that have been authorized to be lawfully marketed in a limited set of other countries. The legislation includes responsible limits to this expedited process, allowing the Secretary of Health and Human Services to decline a reciprocal approval if the Secretary determines a drug or device would not be safe and effective.

As Congress considers a variety of proposals intended to reduce drug costs, we strongly urge policymakers to reject heavy-handed regulatory approaches and instead support the RESULT Act, which would foster innovation and competition by reducing regulatory burdens. We particularly appreciate that this legislation is “aimed at smaller companies, which have a harder time than larger manufacturers navigating and paying for the FDA approval process.”²

¹ Sepp, Pete. “Prescription Drug Costs: Better Ways to Help Patients and Taxpayers.” National Taxpayers Union, December 6, 2018. Retrieved from: <https://www.ntu.org/library/doclib/2018/12/Prescription-Drug-Costs-Better-Ways-to-Help-Patients-and-Taxpayers.pdf> (Accessed July 22, 2019.)

² Leonard, Kimberly. “Ted Cruz bill would speed FDA approval of drugs OK'd in other countries.” Washington Examiner, July 18, 2019. Retrieved from: <https://www.washingtonexaminer.com/policy/healthcare/ted-cruz-bill-would-speed-fda-approval-of-drugs-okd-in-other-countries> (Accessed July 22, 2019.)

Thank you for introducing the RESULT Act, and should you have any questions, I am at your service.

Sincerely,

Andrew Lautz

Policy and Government Affairs Associate

CC: The Honorable Ron Johnson
The Honorable Mike Lee
Chairman Lamar Alexander
Ranking Member Patty Murray