

June 25, 2021

United States Senator Jacky Rosen
144 Russell Senate Office Building
Washington, D.C. 20510

Dear Senator Jacky Rosen:

As representatives of America's nonprofit pharmaceutical organizations, **we applaud your sponsorship of the Expanding Access to Affordable Prescription Drugs and Medical Devices Act.** As our nation reflects on a year with the COVID-19 crisis and its widespread economic impact, the need to ensure a robust drug supply chain and remove cost barriers between Americans and the medicines they need is more urgent than ever. We strongly support this bill, which will help enable our organizations to improve access to affordable drugs and make critical drugs available when needed in the U.S.

Currently, a number of challenges threaten access to essential medicines in the U.S. The price of prescription drugs has steadily risen in recent years, too often forcing patients and families to choose between their financial security and getting the care they need. Moreover, as underscored by the COVID-19 pandemic, vulnerabilities in the drug supply chain limit our nation's ability to respond to public health emergencies, save lives, and keep communities healthy. As Congress considers ways to address rising drug costs and strengthen pharmaceutical supply chains, we believe nonprofit pharmaceutical organizations should be recognized as an important part of the solution.


Our organizations' specific models vary—from developing new products serving the public health, to introducing price competition to high-priced brand-name drugs, to addressing shortages of essential medicines, including those used to manage patients with COVID-19. But we share a fundamental mission: to serve the public by meeting patient needs that are not being met by the commercial market. Free from the need to generate financial returns for investors, nonprofit pharmaceutical organizations are able to pursue research and development and launch products using new distribution methods in areas that traditional for-profit companies typically do not pursue.

This bill presents an opportunity for Congress to support the nonprofit pharmaceutical model. To help nonprofit organizations sustainably develop and market drugs in the U.S., this bill would:


- Clarify that nonprofit pharmaceutical organizations are able to qualify as federally tax-exempt organizations;
- Support the pharmaceutical research, development, and manufacturing of certain drugs and devices by nonprofit pharmaceutical organizations; and
- Support market entry by waiving Food & Drug Administration (FDA) user fees and providing new opportunities for priority FDA review for certain product applications submitted by nonprofit pharmaceutical organizations.

We applaud the introduction of the Expanding Access to Affordable Prescription Drugs and Medical Devices Act and urge its immediate passage. Its provisions are essential to supporting nonprofit pharmaceutical organizations in delivering affordable, accessible drugs to patients and their families in the U.S. Thank you for your leadership on these issues and please do not hesitate to contact us with questions.


Sincerely,

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