

United States Senate  
WASHINGTON, DC 20510

September 17, 2020

The Honorable Alex M. Azar  
Secretary  
U.S. Department of Health and Human Services  
200 Independence Avenue, SW  
Washington, D.C. 20201

Dear Secretary Azar:

We write to express our concerns regarding recent actions from pharmaceutical manufacturers that threaten to undermine the role of contract pharmacies in the 340B Drug Pricing Program. In the midst of the ongoing COVID-19 pandemic, where providers have seen drops in revenue and available resources, it is critically important that 340B covered entities, including federally qualified health centers (FQHCs), FQHC Look-Alikes, children's hospitals, Ryan White HIV/AIDS clinics, and other safety-net hospitals and providers are able to continue to serve the individuals who seek out their care. As these threats to the Program progress, we fear the potential exacerbation of these shortfalls in resources for providers at a time when they are needed most. While we understand that the Health Resources and Services Administration (HRSA) is further investigating these actions, we urge HRSA to take immediate and appropriate enforcement action to halt these tactics and ensure safety-net providers are able to continue providing life-saving medications to patients across the country.

As you are aware, on September 1, 2020, Eli Lilly announced that the company would no longer allow 340B covered entities to receive discounts for products that are shipped to a contract pharmacy, with an exception for insulin. This follows similar actions from AstraZeneca, which announced in August that it would refuse 340B pricing to hospitals with on-site pharmacies for any drugs dispensed through contract pharmacies. Similarly, other companies have imposed additional and burdensome reporting requirements on all contract pharmacy claims. For covered entities, and in particular rural hospitals and other rural covered entities that rely disproportionately on contract pharmacies, these changes could have long-lasting repercussions that will challenge a covered entity's ability to support its community now during this pandemic and in the future.

The Public Health Service Act requires that manufacturers wishing to participate in Medicaid and Medicare Part B enter into agreements with the Department of Health and Human Services (HHS) that "require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." Further, HRSA has recognized the importance of contract pharmacies by

acknowledging such arrangements in current guidance. We believe these recent actions by pharmaceutical manufacturers run counter to the statute and create a dangerous and negative precedent for the 340B Program and the providers and patients it serves.

To ensure pharmaceutical manufacturers continue to comply with the 340B statute and provide discounts to safety-net providers, we call on HRSA to take appropriate, prompt enforcement action to address violations of the Public Health Service Act. We appreciate your attention to this important issue and look forward to partnering with you and stakeholders to ensure the 340B program continues to support access to quality health services with proper oversight and transparency.

Sincerely,

/s/ Tammy Baldwin  
Tammy Baldwin  
United States Senator

/s/ Debbie Stabenow  
Debbie Stabenow  
United States Senator

/s/ Benjamin L. Cardin  
Benjamin L. Cardin  
United States Senator

/s/ Patty Murray  
Patty Murray  
United States Senator

/s/ Ron Wyden  
Ron Wyden  
United States Senator

/s/ Jon Tester  
Jon Tester  
United States Senator

/s/ Doug Jones  
Doug Jones  
United States Senator

/s/ Gary C. Peters  
Gary C. Peters  
United States Senator

/s/ Rob Portman  
Rob Portman  
United States Senator

/s/ Shelley Moore Capito  
Shelley Moore Capito  
United States Senator

/s/ John Thune  
John Thune  
United States Senator

/s/ Susan M. Collins  
Susan M. Collins  
United States Senator

/s/ Jerry Moran  
Jerry Moran  
United States Senator

/s/ M. Michael Rounds  
M. Michael Rounds  
United States Senator

/s/ Joni K. Ernst  
Joni K. Ernst  
United States Senator

/s/ John Boozman  
John Boozman  
United States Senator

/s/ Robert P. Casey, Jr.  
Robert P. Casey, Jr.  
United States Senator

/s/ Cindy Hyde-Smith  
Cindy Hyde-Smith  
United States Senator

/s/ Mark R. Warner  
Mark R. Warner  
United States Senator

/s/ Roger F. Wicker  
Roger F. Wicker  
United States Senator

/s/ Angus S. King, Jr.  
Angus S. King, Jr.  
United States Senator

/s/ Kevin Cramer  
Kevin Cramer  
United States Senator

/s/ Charles E. Schumer  
Charles E. Schumer  
United States Senator

/s/ Thom Tillis  
Thom Tillis  
United States Senator

/s/ Chris Van Hollen  
Chris Van Hollen  
United States Senator

/s/ Sherrod Brown  
Sherrod Brown  
United States Senator

/s/ Elizabeth Warren  
Elizabeth Warren  
United States Senator

/s/ Kirsten Gillibrand  
Kirsten Gillibrand  
United States Senator

Cc: The Honorable Thomas J. Engels, Administrator, Health Resources and Services Administration