

Congress of the United States
House of Representatives
Washington, DC 20515

July 15, 2022

The Honorable Xavier Becerra
Secretary
Department of Health and Human Services
200 Independence Ave SW
Washington, DC 20201

Dear Secretary Becerra:

As leading supporters of the 340B drug pricing program, we urge you to take quick action to protect the integrity of the program and ensure its benefits reach providers and their vulnerable patients, as Congress intended.

Specifically, we urge the Department of Health and Human Services (HHS) and its Office of the Inspector General (OIG) to use current statutory authority to impose civil monetary penalties against all drug manufacturers who have unlawfully overcharged safety net health care providers. Manufacturers have received multiple warnings that their overcharges are unlawful, but still refuse to comply. Further delay of enforcement actions emboldens more manufacturers to begin overcharging safety net providers, threatening the integrity of the entire 340B program.

In February 2021, a majority of the U.S. House of Representatives signed a letter urging HHS to act in response to six drug manufacturers' refusal to honor 340B discounts on their products. Unfortunately, since we sent that letter more than a year ago, at least 12 more manufacturers have announced similar policies restricting access to the 340B program and overcharging providers. These companies' actions have increased costs for federal grantees and other safety net providers and have reduced patient access to care in vulnerable communities.

We appreciate that HHS has taken steps to protect the 340B program. HHS sent warning letters to nine drug manufacturers and referred seven of those companies to the OIG to evaluate whether to impose civil monetary penalties.¹ The OIG is authorized to impose civil monetary penalties against manufacturers that knowingly and intentionally overcharge 340B hospitals and health centers.² However, more than eight months after receiving the first referrals, the OIG has yet to take any enforcement action and these manufacturers continue to unlawfully overcharge safety net providers.

Therefore, we urge OIG to conclude its review of the seven referrals as soon as possible and begin imposing civil monetary penalties against manufacturers it finds in violation of the law. We also request HHS initiate enforcement actions against the remaining eleven drug companies

¹ HRSA Correspondence to Stakeholders, Letters to United Therapeutics Corporation, Sanofi, Novo Nordisk, Novartis Pharmaceuticals Corporation, Eli Lilly and Company, AstraZeneca Pharmaceuticals, Boehringer Ingelheim, and Merck Regarding Sales to Covered Entities through Contract Pharmacy Arrangements, <https://www.hrsa.gov/opa/program-integrity/index.html>.

² 42 U.S.C. § 256b(d)(1)(B)(vi); 42 C.F.R. §10.11(a).

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that have implemented overcharge policies but have not yet been referred to the OIG. These actions are essential to bringing manufacturers back into compliance with their responsibilities under the statute and will deter other manufacturers from pursuing similar unlawful courses of action.

Every day that drug manufacturers violate their obligation to provide these discounted drugs, vulnerable communities, federal grantees, and safety net health care providers are deprived of resources Congress intended to provide. Thank you for your prompt attention to this urgent matter.

Sincerely,



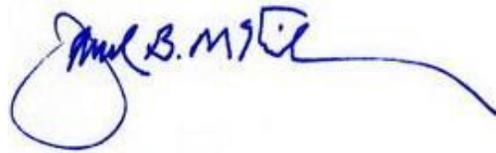
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Member of Congress



Cindy Axne
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Doris Matsui
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David B. McKinley
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Dusty Johnson
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Nanette Diaz Barragán
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Robert B. Aderholt
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Garret Graves
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