

August 26, 2020

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

Dear Secretary Azar:

On behalf of the nation's 340B hospitals, we urge you to protect vulnerable communities from actions taken by five of the nation's largest pharmaceutical manufacturers that undermine access to critical drugs and other health care services. We ask the Department of Health and Human Services (HHS) to use its authority to require that these and other pharmaceutical manufacturers comply with the law. This is particularly critical now as these hospitals need every resource available to care for their patients in vulnerable communities during the COVID-19 public health crisis.

So far, a number of companies are complicit with these unlawful tactics:

#### Eli Lilly

Last month, Eli Lilly announced that effective July 1, 2020, the company will no longer provide 340B pricing on three of its products when purchased by 340B hospitals to be dispensed by 340B contract pharmacies.<sup>1</sup> This refusal to sell a drug at a 340B price is a violation of the statute's requirement that manufacturers offer 340B prices to eligible covered entities. Eli Lilly has left open the possibility that it will extend this policy to other drugs, which include several high-priced drugs to treat diabetes.

#### AstraZeneca

The drug manufacturer AstraZeneca recently announced that, starting October 1, 2020, it will no longer offer 340B pricing to covered entities for any drugs that will be dispensed through contract pharmacies. AstraZeneca sells a wide range of products eligible for 340B pricing, including many costly cancer and diabetes drugs that do not have lower-priced generic alternatives. Cutting off access to 340B pricing for these expensive products would significantly reduce hospital access to program savings, affecting their ability to provide services to patients.

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<sup>1</sup> Limited Distribution Plan Notice for Cialis® (tadalafil) Erectile Dysfunction NDCs, <https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/limited-distribution-plan-notice-cialis.pdf>.

Section 340B(a)(1) of the Public Health Services Act requires manufacturers to sell covered outpatient drugs to covered entities at or below the 340B ceiling price if such drug is made available to any other purchaser at any price.<sup>2</sup> There is no provision under the statute that allows these companies to deny 340B pricing to a covered entity for any drug. Therefore, these policies are a clear violation of the law, and HHS is compelled to take action to stop it from being carried out.

### Merck

On June 29, Merck sent letters to 340B covered entities asking them to submit contract pharmacy claims data for “commonly dispensed” Merck drugs to allow the company to prevent duplicate discounts related to contract pharmacies. Without “significant cooperation” from covered entities, Merck says it “may take further action to address 340B Program integrity.” While Merck did not state that such action would include no longer offering 340B pricing to covered entities for drugs dispensed by contract pharmacies, we are concerned the company appears poised to do so.

### Sanofi

The drug manufacturer Sanofi sent letters last month similar to those sent by Merck threatening to deprive 340B covered entities’ access to discounted drugs for dispensing through contract pharmacies if the claims data demanded are not supplied to the company by October 1.

### Novartis

In a similar manner, Novartis recently sent letters to 340B covered entities requiring them to submit all 340B claims data originating from contract pharmacies beginning October 1, stating that 340B discounts will be unavailable to entities that fail to do so.

As you are aware, Congress created the 340B drug pricing program to allow hospitals and other covered entities serving vulnerable populations “to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”<sup>3</sup> Covered entities use the savings from the high prices of prescription drugs enabled under the 340B drug program to support care for vulnerable communities in a variety of ways, including supporting clinic and medical services that would otherwise be unavailable.

If left unaddressed, these actions will open the way for other drug manufacturers to deny discounts for other products. This is clearly contrary to the intent of the 340B program

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<sup>2</sup> 42 U.S.C. § 256b(a)(1).

<sup>3</sup> H.R. Rep. 102-384(II) at 12 (1992).

and will result in significant harm to the millions of patients and communities who rely on providers that participate in the program for their care.

At a time when our nation and our hospitals are focused on confronting the global pandemic of COVID-19 and dealing with the continuing increase in prescription drug costs, we urge the Department to use its authority to address these troubling actions and assure that the pharmaceutical industry does not prioritize excess profits over care for vulnerable communities. We thank you for your continued leadership.

Sincerely,

340B Health  
America's Essential Hospitals  
American Hospital Association  
American Society of Health-System Pharmacists  
Association of American Medical Colleges  
Catholic Health Association  
Children's Hospital Association

cc: Eric D. Hargan, Deputy Secretary, Department of Health and Human Services  
Thomas J. Engels, Administrator, Health Resources and Services Administration  
Krista Pedley, Director, Office of Pharmacy Affairs, Health Resources and Services Administration