

April 20, 2021

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

Dear Secretary Becerra,

On behalf of the undersigned organizations, we very much appreciate the Department of Health and Human Services' (HHS) recent efforts to support the 340B program. However, to date, none of those efforts has deterred the six drug companies (Eli Lilly and Company, Sanofi-Aventis U.S. LLC, AstraZeneca PLC, Novartis Pharmaceuticals Corporation, United Therapeutics Corporation, and Novo Nordisk, Inc./Novo Nordisk Pharma) from refusing to provide statutorily required drug discounts to 340B hospitals that are dispensing those drugs through community pharmacies. Our organizations represent virtually every hospital and health system — as well as the skilled pharmacists who work there — that participate in the 340B program and dispense drugs through a community pharmacy. On behalf of our members we are requesting that HHS immediately take steps to halt this detrimental and illegal conduct.

As you are aware, Congress adopted the almost 30-year-old 340B program in order to require drug companies to give deep discounts to non-profit and public hospitals that disproportionately serve low income communities. The purpose of the program is to provide resources so that they can reach more patients in these communities and provide more comprehensive services. H.R. REP. NO. 102-384(II), at 12 (1992). And that is exactly what they are doing. 340B hospitals provide a substantial portion of all hospital services to Medicaid patients and uncompensated care and are more likely to offer highly specialized, but under-reimbursed, services like burn and trauma care as well as HIV/AIDS and inpatient psychiatric care.¹ The program has been beneficial to patients in the hospitals' communities, and Congress expanded it when enacting the Affordable Care Act in 2010 to include more hospitals serving rural areas.

The 340B program provides discounts for drugs prescribed by a participating hospital regardless of whether the drugs are dispensed at the hospital or at a pharmacy in a different location that the hospital contracts with to provide such services. These community pharmacies are particularly important in communities where patients face transportation barriers, whether in rural areas where patients often do not live near the hospital, or in urban areas with poor public transit systems. For more than 20 years, HHS has consistently provided guidance affirming the statutory requirement that drug

¹ Dobson DaVanzo, The Role of 340B DSH Hospitals in Serving Medicaid and Low-income Medicare Patients (2020) at https://www.340bhealth.org/files/340B_and_Medicaid_and_Low_Income_Medicare_Patients_Report_7.10.2020_FINAL_.pdf; L&M Policy Research, Analysis of Disproportionate Share Hospital Services to Low-income Patients (2018) at https://www.340bhealth.org/files/340B_Report_03132018_FY2015_final.pdf.

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companies must provide discounts to hospitals that have these arrangements with community pharmacies, and the industry has complied.

In May 2020, Eli Lilly and Company decided to test the waters as to whether HHS would permit it to deny discounts for drugs dispensed by contract pharmacies. It informed the Health Resources and Services Administration (HRSA) that it intended to adopt a policy of withholding 340B discounts for a single drug, Cialis[®], when dispensed via a community pharmacy, and made it clear that it intended to proceed unless HRSA objected. Unfortunately, instead of notifying Lilly that its policy was illegal, HRSA simply sent a letter discouraging Lilly from adopting the policy. Then when Lilly implemented the policy, HRSA posted Lilly's letter on its website, which allowed other drug companies to learn that Lilly was proceeding with this policy. Having not been clearly deterred by HRSA, Lilly quickly expanded its policy to all of its drugs, and, not surprisingly, five additional drug companies followed Lilly's lead.

When Lilly announced its policy last summer, our associations immediately urged HHS and HRSA to take action to stop this illegal conduct. After months of waiting for action and enduring the enormous financial consequences the policies had for the 340B hospitals and health systems we represent during the height of a devastating national pandemic, we reluctantly filed suit in the Northern District of California. That action sought a ruling that the six drug companies' refusal to provide 340B providers 340B discounts for drugs dispensed through community pharmacies was illegal and an order requiring HHS to develop an enforcement plan aimed at stopping the drug companies from continuing to implement these illegal policies. See Complaint, *Am. Hosp. Ass'n v. Azar*, No. 4:20-cv-8806 (N.D. Cal. Dec. 11, 2020).

Less than three weeks after the lawsuit was filed, the HHS General Counsel issued an advisory opinion agreeing with us that the six drug companies' conduct is illegal. Nevertheless, HHS took no action to halt this conduct. Relying on the existence of the advisory opinion, representations by the Department of Justice that there was an effective avenue of redress, and the fact that a new administration had just been installed, the court dismissed the case. The court did so "without prejudice" so that we could refile if HHS continues to take no action. As the court stated, "plaintiffs may be able to maintain a narrower action seeking general enforcement of the statute in the future." *Am. Hosp. Ass'n v. Azar*, No. 4:20-cv-8806, 2021 WL 616323, at *8 (N.D. Cal. Feb. 17, 2021).

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The avenue of redress so heavily relied upon was publication of the long-awaited Alternative Dispute Resolution (ADR) regulation just days after the lawsuit was filed. See 340B Drug Pricing Program; Administrative Dispute Resolution Regulation, 85 Fed. Reg. 80,632 (Dec. 14, 2020). However, not only has the ADR regulation never been implemented (HRSA never appointed an ADR panel to resolve disputes), but the regulation is being challenged in three separate lawsuits filed by Lilly, Sanofi, and the Pharmaceutical Research and Manufacturers of America, and has been preliminarily enjoined by the court in the lawsuit brought by Lilly. It is possible that the courts in the other cases will do the same. In any case, it is not likely that this avenue of redress will be available anytime in the foreseeable future, thus exacerbating the harm being caused by these drug companies' refusal to obey the law and making it imperative the HHS take action to halt their conduct.

The General Counsel's advisory opinion agreed with us that the 340B law requires drug companies to offer 340B discounts to participating hospitals for drugs dispensed through community pharmacies. Moreover, HHS has the tools to address this illegal behavior. To that end, we are respectfully requesting that HHS immediately and definitively state that these refusals to provide discounts are illegal and take the action Congress specifically prescribed to address this type of situation — impose civil money penalties.

We appreciate HHS' efforts to support the 340B program and the vulnerable communities it serves. Those efforts have never been more crucial as 340B hospitals and health systems, along with the rest of the health care providers, continue to weather the effects of the ongoing pandemic.

Sincerely,

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