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(866) 423-7849

Lawsuit Against HHS Highlights 340B Drug Pricing Dispute

Announcer:
You're listening to The Drug Report on ReachMD, hosted by Linda Bernstein, Pharm.D., Clinical Professor on the Volunteer Faculty of the School of Pharmacy, University of California, San Francisco.

Dr. Bernstein:
Welcome to The Drug Report.

A federal lawsuit was filed on December 11, 2020 against the U.S. Department of Health and Human Services (HHS) by five national hospital organizations and an organization of hospital pharmacists representing participants in the 340B drug pricing program. 340B requires drug companies to offer discounts on outpatient drugs to hospitals and other providers that serve patient communities in need, including those in rural areas. These savings enable hospitals to provide more comprehensive health care and support to patients – including free or low-cost drugs – without incurring costs for taxpayers. The suit alleges that HHS has failed to enforce program requirements and halt drug company actions that undermine the program. Three 340B hospitals serving patient communities in need that have been harmed by the companies' refusals to provide discounts on prescription drug dispensed at community-based pharmacies as stipulated by the 340B program have also joined the lawsuit.

In addition, a collection of 27 states and the District of Columbia wrote to the HHS urging the agency to rein in drug makers they say are restricting access to 340B discounted drugs in a letter on December 14. California Attorney General Xavier Becerra and soon to be President-elect Joe Biden's nominee to lead HHS stated, "Discounts afforded under the 340B Drug Pricing Program are more critical now than ever. We call on HHS to hold these non-compliant drug manufacturers accountable and provide immediate relief for healthcare centers and the Americans they serve."

In a rare bipartisan move, a group of 243 House lawmakers and 28 senators sent letters last week to Department of Health and Human Services Secretary Alex Azar over a series of moves drug companies have made on the 340B drug discount program. The lawmakers urge swift action from Azar to restrict the moves, which they say are hurting providers.

The letter stated, "To ensure pharmaceutical manufacturers continue to comply with the 340B statute and provide accounts to safety-net providers, we call on [Health Resources and Services Administration] to take appropriate, prompt enforcement action to address violations of the Public Health Service Act."

The lawsuit was filed by 340B Health, the American Hospital Association (AHA), the American Society of Health-System Pharmacists (ASHP), America's Essential Hospitals (AEH), the Association of American Medical Colleges (AAMC), and the Children's Hospital Association (CHA) in the U.S. District Court for the Northern District of California. Avera St. Mary's Hospital in Pierre, S.D., Riverside Regional Medical Center in Newport News, Va., and St. Mary's Medical Center in San Francisco are the individual hospital plaintiffs in the lawsuit.

The issue here is that since July, a growing number of pharmaceutical companies have unilaterally refused to provide discounts to 340B hospitals on drugs that are dispensed at community-based pharmacies. Many hospitals, including the three named as plaintiffs, rely on these 340B savings because they enable them to continue providing crucial care to patients in need.

HHS has yet to take action on the matter despite frequent communications urging it to enforce the law and block these actions by the drug companies. The 340B law does not allow drug companies to condition discounts on the places where patients obtain these drugs.

According to the American Society of Hospital Pharmacists, one of the plaintiffs in the lawsuit, the court is asked to order that HHS

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require these drug companies to provide 340B discounts on the drugs dispensed at community-based pharmacies and issue refunds to the hospitals that were refused discounts. It also asks for an order requiring HHS to refer the drug companies responsible for these violations to the HHS Office of Inspector General (OIG) to assess penalties the law requires.

Paul W. Abramowitz, Pharm.D., Sc.D. (Hon.), FASHP, ASHP's CEO stated, "Hospital and health-system pharmacists have seen first-hand how critical the 340B program is in serving low-income patients in rural and urban areas throughout our country. Our patients depend on this program, which ensures that our most vulnerable populations have access to the care they need. Now more than ever, as we navigate a public health emergency, it is essential that the program be implemented as Congress intended it."

The lawsuit's action challenges HHS's assertion that they lack the authority to require six pharmaceutical companies—Eli Lilly and Company ("Lilly"), Sanofi-Aventis U.S. LLC ("Sanofi"), AstraZeneca PLC ("AstraZeneca"), Novartis Pharmaceuticals Corporation ("Novartis"), United Therapeutics Corporation ("United Therapeutics"), and Novo Nordisk, Inc. and Novo Nordisk Pharma ("Novo Nordisk") (collectively, the "Drug Companies")— to offer certain drugs to covered hospitals and other facilities at statutorily required discounted prices when the drugs are dispensed through community pharmacies via contractual arrangements.

The 340B Program directs the Secretary to require as a condition of participating in Medicaid and Medicare Part B that pharmaceutical manufacturers sell outpatient drugs at a discount to certain public and not-for-profit hospitals, community health centers, and other federally funded clinics that serve large numbers of patients with low income, including many living in rural communities, in order to increase the funding these entities have available to meet the needs of their patients.

The hospitals and other facilities that are eligible for and enroll in the 340B Program are known as "covered entities." The 340B statute requires the setting of "ceiling prices," *i.e.*, the maximum prices that drug companies can charge to covered entities for covered outpatient drugs, to ensure that covered entities have access to drugs at a lower cost to enable these covered entities to "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." 340B covered entities dispense covered outpatient drugs to their patients through in-house pharmacies or through community pharmacies that have entered into written contracts with the covered entity (known as, "contract pharmacies"). Under such arrangements, the covered entity orders and pays for the 340B drugs, which are then shipped from the manufacturer to the contract pharmacy, whose function is to dispense the drugs to the covered entity's patients.

The 340B statute requires manufacturers to offer 340B pricing to covered entities irrespective of how the drugs are dispensed and requires the Secretary to ensure the availability of those statutorily required discounts. HHS recognized the importance of contract pharmacies to the 340B Program when the program began in 1992 and issued its first guidance formally recognizing contract pharmacies in 1996.

In 1996 and again in 2010, HHS recognized that under section 340B, if a covered entity using contract pharmacy services requests to purchase a covered outpatient drug from a participating manufacturer, the statute directs the manufacturer to sell the drug at a price not to exceed the statutory 340B discount price.

According to the lawsuit, in defiance of their statutory obligations and despite this long history of regulatory guidance, the Drug Companies have instituted policies refusing to offer 340B discounts for covered drugs if a covered entity dispenses the drug through a contract pharmacy.

Despite Plaintiffs' and others' repeated requests that HHS enforce the 340B statute and require the Drug Companies to sell 340B drugs to covered entities at or below 340B ceiling prices regardless of whether the drugs are to be dispensed via contract pharmacies, HHS has refused to take action against the Drug Companies or to even inform them that their conduct violates the 340B statute. Instead, on July 8, 2020, HHS determined that they lack the authority to require the Drug Companies to sell 340B drugs at or below 340B ceiling prices when dispensed through contract pharmacies.

HHS' refusal to require the Drug Companies to sell 340B drugs to covered entities at or below 340B ceiling prices when dispensed through contract pharmacy arrangements is causing significant harm to the Association Plaintiffs' hospital members and pharmacists and to the Hospital Plaintiffs and, by extension, their patients.

Plaintiffs have no cause of action directly against the Drug Companies for their refusal to comply with the 340B statute. They must rely on the HHS to correctly interpret and apply the statute.

For The Drug Report, I'm pharmacist, Dr. Linda Bernstein.

Announcer:
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