

Manufacturers Are “Winning” in the 340B Drug Discount Dispute

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Section 340B of the Public Health Service Act has grown significantly since its enactment in 1992 – both in the number of covered entities eligible to participate and in the volume of drugs purchased through the program. The rapid growth in the discount drug program has caused a series of legal challenges between manufacturers and providers.

Manufacturers secured an important victory on May 21, 2024, when the U.S. Court of Appeals for the District of Columbia Circuit upheld the U.S. District Court for the District of Columbia’s decision in *United Therapeutics Corporation v. Carole Johnson, et al./Novartis Pharmaceuticals v. Carole Johnson* (consolidated cases). The D.C. Circuit affirmed that Section 340B does not categorically prohibit manufacturers from imposing conditions on the distribution of covered drugs to covered entities. This is the second federal appeals court to rule on the ongoing 340B drug discount dispute.

The Recent Dispute

Novartis Pharmaceuticals Corporation (Novartis) and United Therapeutics Corporation (United Therapeutics) sell drugs subject to the discounts set forth in Section 340B of the Public Health Service Act. In 2020, both companies began to impose certain restrictions, limiting the number and kinds of contract pharmacies to which they would ship orders. In response, the U.S. Department of Health and Human Services (HHS) issued an advisory opinion stating that Section 340B requires manufacturers to deliver covered drugs to any contract pharmacies with which a covered entity chooses to partner. HHS then issued enforcement letters to Novartis and United Therapeutics, threatening penalties if the companies failed to lift those restrictions.

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The district court judge vacated the enforcement letters and issued a declaratory judgment that the conditions set by the manufacturers are lawful.

Under Section 340B, manufacturers are required to sell certain drugs at discounted prices to select health care providers or “covered entities” that primarily serve low-income individuals. To facilitate the distribution of these drugs, the providers often contract with outside pharmacies. However, according to manufacturers, these partnerships have left the Section 340B program vulnerable to abuse and have resulted in great cost to manufacturers. In response, manufacturers have imposed their own contractual terms on providers, including limits on the number of pharmacies to which the manufacturers will make shipments. Here, the government/HHS argued that these restrictions violate the statute. The district court held that the statute did not prohibit manufacturers from limiting the distribution of discounted drugs by contract. The D.C. Circuit agreed.

Judges Gregory Katsas, J. Michelle Childs, and Neomi Rao stated in an opinion that neither Novartis nor United Therapeutics violated Section 340B when they put certain contractual conditions on the number and kinds of contract pharmacies they ship orders to. Judge Gregory Katsas further stated that the conditions at issue in this case do not violate Section 340B on their face, but did acknowledge that there could be “other, more onerous conditions [that] might violate the statute” or that the conditions imposed in this case may violate Section 340B as applied in particular circumstances.

What to Know About the Ongoing 340B Dispute

- The D.C. Circuit is the second of at least three federal courts of appeals to consider the scope of 340B contract pharmacy requirements.
- The U.S. Court of Appeals for the Third Circuit is the first federal appeals court to weigh in on the 340B drug discount dispute. The Third Circuit also sided with manufacturers who argued they are not required to supply lower-priced medications to an unlimited number of contract pharmacies, and HHS’s attempts to enforce manufacturers to do so are unlawful.
- In October 2022, the Seventh Circuit heard arguments in a similar case. There, manufacturer Eli Lilly stated it would only send 340B drugs if the covered entity lacks an in-house pharmacy or completely owns the contract pharmacy to assure its compliance with the program. The Seventh Circuit has yet to issue its decision.
- As of now, manufacturers are “winning” in the ongoing 340B drug discount dispute, as federal courts are siding with manufacturers. However, there is potential for an eventual circuit split on the dispute and an ultimate weigh-in from the U.S. Supreme Court.

For other developments on the 340B Drug Pricing Program, see our previous alert regarding the final rule for the 340B ADR process. The final rule will be effective on June 18, 2024.

Wiley’s PBM Contracting team of experienced attorneys and advisors is closely monitoring the 340B Drug Pricing program and is available to assist with any questions.