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Supreme Court Rejects 340B Pricing Case

Covered Entities Have No Right to Sue Manufacturers to Enforce Pricing Agreements; HHS Retains Exclusive Authority Over the Drug Discount Program

In a unanimous opinion, the Supreme Court last week held that 340B covered entities may not sue drug manufacturers for alleged violations of the 340B Pharmaceutical Pricing Agreement (PPA). Only the federal government may enforce the terms of that agreement. This decision stems a potential flood of private litigation against drug and biologics manufacturers regarding 340B and Medicaid pricing. Click here to read the opinion.

Justice Ginsburg authored the Court's 8-0 opinion reversing the Ninth Circuit Court of Appeals. Justice Kagan took no part in consideration of the case.

Background

340B is a federal drug discount program that permits qualified safety net providers to purchase products from participating manufacturers at discounted prices. The 340B statute (42 U.S.C. §256b) requires manufacturers to steeply discount drugs to "340B covered entities" as a condition of Medicaid coverage. Manufacturers opt into the program by signing a form agreement, the PPA, with the Secretary of HHS. Covered entities are not party to the agreement, but alleged in this suit that they are "third party beneficiaries" of PPAs under federal common law.

Several 340B covered entities in Santa Clara County, California, sued nine drug manufacturers alleging that the companies had overcharged them for drugs in violation of the PPA. The covered entities alleged not only that the manufacturers charged them more than was permitted under the agreement, but that the manufacturers had miscalculated Average Manufacturer Prices, Best Prices and Unit Rebate Amounts, the constituent parts of the 340B ceiling price (and critical Medicaid rebate metrics).

The manufacturers argued that because the 340B statute contains no private right of action, the covered entities may not find one in contract and therefore had no right to sue to enforce the PPAs. They also argued that private lawsuits to set drug pricing policy would disrupt the administration of both

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the 340B and Medicaid programs. The United States filed an *amicus* brief generally agreeing with the manufacturers' positions.

The Covered Entities Have No Right To Sue to Enforce the PPAs

The Court recognized that PPAs simply reflect the requirements of the 340B statute and establish the drug manufacturer's intent to participate in the 340B program. The covered entities' allegations of overcharging were rooted in the requirements of the 340B statute, not in any independent substantive obligation of the PPAs. Because there is no private right of action in the federal statute, the Court reasoned, the covered entities cannot overcome that obstacle by suing to enforce the contract instead as alleged third-party beneficiaries. Such lawsuits would be inconsistent with the legislative scheme Congress contemplated.

Private Enforcement Would Undermine HHS Administration of National Pricing Policy

The Court was clearly troubled that third-party lawsuits would disrupt HHS's administration of the national 340B and Medicaid programs. Congress made HHS the administrator of both programs because the interdependence of the two programs' pricing components[1] requires "'adjudication of rights under one program [to] proceed with an eye towards any implications for the other.'" Whereas HHS is well-positioned to harmonize the competing interests, private enforcement could "spawn a multitude of dispersed and uncoordinated lawsuits" and risk "conflicting adjudications."

"Far from assisting HHS" in meeting its enforcement burden, the Court wrote, "suits by 340B entities would undermine the agency's efforts to administer both Medicaid and §340B harmoniously and on a uniform, nationwide basis."

Implications for Drug Manufacturers

The most important implication of this ruling is that the drug and biologic industries will not face a flood of potentially costly and disruptive litigation by covered entities. Discovery into the AMP and Best Price calculation methodologies of nine manufacturers had already begun. Attempts by federal courts to divine "correct" methods for calculating these metrics (particularly in a period before AMP and BP regulations were issued by CMS) would have injected significant chaos into manufacturers' participation in 340B, Medicaid and perhaps even Medicare Part B.

That Santa Clara's attempt to enforce the PPA by private lawsuit was rejected by the Supreme Court does not absolve drug and biologic manufacturers of the obligation to accurately establish ceiling prices. Enforcement authority over the terms of the 340B statute and PPA lies with the Secretary of HHS and her designee, HRSA. HRSA and/or the HHS OIG may take steps to investigate allegations of overcharging at their discretion.

Importantly, the Affordable Care Act includes numerous 340B program "integrity provisions." These provisions call on HHS to create mechanisms that, among other things, ensure that covered entities are not overcharged. HRSA has

[1] AMPs and Best Prices are used to set both Medicaid rebate liability and 340B ceiling prices. This interdependence does not mean that the interests of the 340B community and state Medicaid programs are always aligned, however. Covered entities may prefer one interpretation of AMP over that favored by Medicaid, for instance. HHS is well positioned to balance those interests; federal courts, the Supreme Court noted, "as first line decisionmakers are not similarly equipped to deal with the whole picture."

sought comment on administrative dispute resolution and civil money penalties for noncompliant manufacturers. Otherwise, no steps have been taken by HHS to implement the 2010 340B integrity provisions. We expect that in the coming months HRSA will issue policy positions and/or proposed rules on these important program safeguards.

Until it does, we recommend that manufacturers continue to strengthen their AMP, BP and URA calculation methodologies and processes to ensure that 340B entities are not overcharged. Further, we recommend that manufacturers consider the intent of Congress as expressed in the Affordable Care Act that overcharges be reconciled. We will know more about the extent of the requirement and operation of the mechanism when HRSA publishes guidance or a proposed rule.

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King & Spalding drafted the *amicus* briefs submitted by PhRMA in this litigation (for *certiorari* and on the merits). For copies of those briefs, click here (for *certiorari*) and here (on the merits).