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Supreme Court Rules 340B Covered Entities Cannot Sue Drug Manufacturers Over Drug Pricing Disputes

Authors: Helen R. Pfister | William A. Connelly | Susan R. Ingargiola

On March 29, 2011, the Supreme Court, in a unanimous opinion by Justice Ruth Bader Ginsburg, ruled that safety-net health care providers, such as eligible hospitals and community health centers, enrolled in the federal 340B Drug Discount Program (the "340B Program") do not have a right to sue drug manufacturers for alleged overpricing of drugs they sell under the program.

The Supreme Court issued the ruling in *Astra USA Inc. v. County of Santa Clara*, a class action suit in which Santa Clara County, on behalf of the health care providers enrolled in the 340B Program ("Covered Entities") in California and also on behalf of California county governments that provide funding for Covered Entities, alleged that nine drug manufacturers charged them prices above the 340B Program's statutorily defined maximum prices, which are known as "340B Ceiling Prices."

Under the 340B Program, authorized by Section 340B of the Public Health Service Act ("Section 340B"), pharmaceutical manufacturers provide up-front discounts on covered outpatient drugs purchased by Covered Entities. While participation in the program is voluntary, manufacturers may not participate

in the Medicaid program unless they participate in the 340B Program. Manufacturers opt into the 340B Program by signing a form Pharmaceutical Pricing Agreement ("PPA"). PPAs are uniform agreements that recite the responsibilities Section 340B imposes on drug manufacturers and the federal Department of Health and Human Services ("HHS"), which oversees the 340B Program.

By statute, if a manufacturer overcharges a Covered Entity, HHS may require the manufacturer to reimburse the Covered Entity. HHS may also terminate the manufacturer's PPA, which would terminate the manufacturer's eligibility for Medicaid coverage of its drugs. Currently, HHS handles overcharge complaints through informal procedures.

No Private Right of Action for Covered Entities

Astra USA Inc. v. County of Santa Clara presented the question whether Covered Entities, though accorded no right to sue for overcharges under Section 340B itself, may nonetheless sue allegedly overcharging manufacturers as third-party beneficiaries of the PPAs into which the manufacturers enter with HHS. In other words, whether Covered Entities can enforce contracts between drug manufacturers and HHS. The standard for whether a third party beneficiary has a private right of action is whether the parties to the contract intended for them to have such enforceable rights.

The district court for the Northern District of California dismissed the class action complaint, concluding, among other things, that the PPAs did not reflect any intent to confer enforcement rights on the Covered Entities. The U.S. Court of Appeals for the Ninth Circuit, on the other hand, held that Covered Entities, although they have no right to sue under the statute, could, in fact, enforce the PPA as third-party beneficiaries.

The Supreme Court reversed the Ninth Circuit's decision, finding a private right of action to be both incompatible with the legislative scheme of Section 340B and likely to undermine HHS's ability to administer the 340B Program.

Incompatibility of Private Suits with the Legislative Scheme of Section 340B

Noting that the PPAs that manufacturers enter into with HHS under the 340B Program simply incorporate Section 340B's statutory obligations and record the manufacturers' agreement to abide by them, the Supreme Court held that a third-party private contract action to enforce the statutory obligation on drug manufacturers to ensure that Covered Entities pay no more for any drug than the Section 340B Ceiling Price would be inconsistent with the legislative scheme of Section 340B. The legislative scheme of Section 340B, the Court held, vests HHS with authority to oversee compliance with the 340B Program and assigns no auxiliary enforcement role to Covered Entities.

As further indication of the incompatibility of private suits with Section 340B, the Supreme Court highlighted that the Medicaid Rebate Program statute prohibits HHS from disclosing pricing information in a form that could reveal the prices a manufacturer charges for its drugs. If Congress meant to leave open the prospect of third-party beneficiary suits by Covered Entities, the Court found, it likely would not have barred Covered Entities from obtaining the information necessary to determine whether their rights were violated in the first place.

The Undermining Effect of Suits by Covered Entities

In its opinion, the Court noted that HHS's Office of the Inspector General has published reports finding that HHS lacks the oversight mechanisms and authority to ensure that Covered Entities pay at or below the 340B Ceiling Price. But the Court found that rather than assisting HHS, suits by Covered Entities would undermine the agency's efforts to administer both Medicaid

and Section 340B harmoniously and on a uniform, nationwide basis. According to the Court, "Congress did not respond to the reports of inadequate [HHS] enforcement by inviting [Covered Entities] to launch lawsuits in district courts across the country." Rather, in the Affordable Care Act ("ACA"), Congress directed HHS to create a formal dispute resolution procedure, institute refund and civil penalty systems, and perform audits of manufacturers. Congress thus opted to strengthen and formalize HHS's enforcement authority, to make the new adjudicative framework the proper remedy for Covered Entities alleging overcharges and other violations of the 340B Program's discounted pricing requirements and to render HHS's resolution of Covered Entities' complaints binding, subject to judicial review under the Administrative Procedure Act.

While the formal procedures for resolving Covered Entities' overcharge claims required by the ACA are not yet in place, HHS will be working to implement them in the coming months.

To read the Supreme Court's opinion, click here.