

Alerts and Updates

SUPREME COURT DECIDES 340B ENTITIES CANNOT SUE PHARMACEUTICAL MANUFACTURERS FOR NONCOMPLIANCE WITH PHARMACEUTICAL PRICING AGREEMENT

April 1, 2011

On March 29, 2011, the Supreme Court of the United States decided *Astra USA, Inc. v. Santa Clara County*.¹ In a unanimous decision, the Court determined that 340B entities, including public hospitals and community health centers that provide health services to the poor, could not sue pharmaceutical manufacturers for failing to comply with the Pharmaceutical Pricing Agreement (PPA) that the manufacturers entered into with the Health Resources and Services Administration (HRSA), a unit of the Department of Health and Human Services (HHS).

In essence, the 340B program provides that covered entities, such as the plaintiffs, are to be charged no more than the pre-determined ceiling price derived from the "average" and "best" prices and rebates calculated under the Medicaid Drug Rebate Program. If a manufacturer overcharges a covered entity, HRSA may require the manufacturer to reimburse the covered entity.

Santa Clara County—an operator of several 340B entities—sued, as an alleged third-party beneficiary, Astra and eight other pharmaceutical manufacturers, alleging the companies overcharged 340B healthcare facilities in violation of the PPAs that the companies signed. Both Astra and Santa Clara County agreed that the 340B statute does not provide for a private right of action.

Justice Ginsburg determined that "the absence of a private right to enforce the statutory ceiling price obligations would be rendered meaningless if 340B entities could overcome the obstacle by suing to enforce the contract's ceiling price obligations instead. The statutory and contractual obligations, in short, are one and the same." Justice Ginsburg rejected the contention of Santa Clara County that allowing a private enforcement of the contractual rights under the PPA would not undermine Congress' contemplated intent of "centralized enforcement in the government." In addition, Justice Ginsburg ruled that HRSA and HHS were best suited, rather than the courts, for dealing with the whole picture related to Medicaid reimbursement. The Court, however, took no position on how this ruling might affect the average wholesale price litigation currently pending in numerous jurisdictions.

For Further Information

If you have any questions about this *Alert*, please contact [Frederick \(Rick\) R. Ball](#), any [member](#) of the [Pharmaceutical, Pharmacy & Food](#) industry group or the attorney in the firm with whom you are regularly in contact.

Note

1. *Astra USA, Inc. v. Santa Clara County*, 2011 U.S. LEXIS 2592 (U.S. Mar. 29, 2011). Justice Kagan took no part in the consideration or decision of the case.

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