Astra USA, Inc. v. *Santa Clara County, CA*: The Supreme Court Rejects Suits by Third-Party Beneficiaries to Enforce Requirements of Section 340B Contracts Between Pharmaceutical Manufacturers and HHS

On March 29, 2011, in a unanimous decision authored by Justice Ruth Bader Ginsberg, the Supreme Court, in *Astra USA, Inc.* v. *Santa Clara County, CA*, No. 09-1273, held that third-party beneficiaries of government contracts between pharmaceutical manufacturers and the Secretary of the Department of Health and Human Services (HHS) could not bring suit to enforce those contracts. The Court reasoned that, because the plaintiff-beneficiaries of the government contracts have no statutory right to sue under the federal statute that specified the terms of the contract, the beneficiaries may not circumvent the absence of a statutory cause of action by suing to enforce the contract's terms in a breach of contract suit. The decision not only resolves important questions of interpretation for litigation involving government contracts that implement federal statutes, but the decision is likely to have significant consequences for third-party beneficiary challenges under other federal health care programs and *qui tam* actions under the Medicaid and other programs.

The *Santa Clara* case concerned a dispute over form contracts that implement a statute, Section 340B of the Public Health Service Act, 42 U.S.C. § 256b (the 340B statute), that requires pharmaceutical companies to charge no more than a ceiling price to entities such as public hospitals and community health centers. The 340B statute requires drug manufacturers, as a condition of their participation in the much-larger Medicaid program, to enter into contracts obligating them to charge prices no higher than a "340B ceiling price" for outpatient pharmaceuticals sold to

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eligible entities. The statute prescribes a formula for calculating the ceiling price, which borrows heavily from the formula for calculating Medicaid rebates that are payable to the states under the prior-enacted Medicaid program. In turn, the government contract incorporates the 340B statute's pricing formula verbatim.

The plaintiffs in the *Santa Clara* case are two California counties that fund 340B entities. They allege that the drug manufacturer defendants breached the contract by miscalculating the 340B ceiling price. Although the complaint initially asserted other causes of action (which were dismissed by the district court and not appealed), the Supreme Court's decision addressed only a breach of contract count: the plaintiffs' contention that defendants charged prices higher than the 340B ceiling price, resulting in a breach of the contract.

The Ninth Circuit held that, even though the statute does not authorize private suits, plaintiffs could sue under federal common law as third-party beneficiaries of the government contract. The pharmaceutical companies sought Supreme Court review, contending that the Ninth Circuit's decision would circumvent Congress' intent not to provide a right to sue under the statute. The companies observed that a breach of contract claim makes the same allegations, relies on the same evidence, and seeks the same relief as a claim under the 340B statute.

The Supreme Court unanimously agreed. After recognizing that the 340B statute itself does not confer a right to sue, the Court reasoned that "it would make scant sense to allow [the plaintiffs] to sue on a form contract implementing the statute, setting out terms identical to those contained in the statute."[1] In rejecting the plaintiffs' argument that they could sue as intended beneficiaries of the contract, the Court emphasized that the contracts "simply incorporate statutory obligations and record the manufacturers' agreement to abide by them."[2] Because the suit under the contract would "in essence" be "a suit to enforce the statute itself," the Court concluded that the lack of a private right of action under the statute "would be rendered meaningless" if the plaintiffs could enforce the contract's ceiling price requirements under a breach of contract theory.[3]

The Court underscored that the statutory scheme contemplates "centralized enforcement in the government."[4] The Court explained that: (a) HHS administers both the drug pricing program and the Medicaid program; (b) the statutes mandate that pricing information must be kept confidential from the beneficiaries; and (c) the Patient Protection and Affordable Care Act addressed concerns about HHS's oversight of the program by enhancing HHS's administrative enforcement authority, not by authorizing suits by covered entities.

The case represents a significant victory for the nine pharmaceutical companies that had been sued and were subjected to burdensome and costly discovery in the district court. In addition to foreclosing these and other suits by 340B entities against pharmaceutical companies, the Court's decision is significant because it resolved a long-standing division in the circuits on the question of whether beneficiaries to a federal government contract may sue to enforce a contract that implements statutory requirements when the statute itself does not authorize a cause of action. This issue had arisen under a variety of federal programs, including housing, labor, and other pharmaceutical pricing programs. In definitively answering that question in the negative, the Court determined that, where a statute mandates the terms of a government contract, a suit to enforce the statute and a suit to enforce the contracts are "in substance one and the same."[5]

1 Slip op. at 2.

2 *Id.* at 6.

3 *Id.* at 6-7.

4 *Id.* at 8.

5 *Id.* at 2.

The Court's decision is particularly likely to have implications for other litigation involving the pharmaceutical industry. First, the Court's decision could be helpful in *qui tam* litigation relating to the Medicaid rebate program. The ceiling prices under the 340B program are derivative of the methodology for calculating Medicaid rebates. As the Court explained, "the amount of the rebates [under the Medicaid program] depends on the manufacturer's 'average' and 'best' prices," as defined in the Medicaid Rebate Act.[6] The Court characterized the calculation of these components of the Medicaid rebate calculation as "a complex enterprise" involving "recourse to detailed information about the company's sales and pricing."[7] Under the False Claims Act, reasonable interpretations of complex statutory requirements may preclude a finding of a false or fraudulent claim or the requisite scienter as a matter of law.[8] Accordingly, the Court's description of the average manufacturer price and best price calculations as "complex" may be helpful in negating these elements of a false claim.

Second, although the Court declined to consider the question of whether states and other third parties cannot sue for breach of the Medicaid Rebate Agreement, the Court's language supports resolving that issue in favor of pharmaceutical companies. Notably, the characteristics of the government contract that the Court cited to preclude third-party beneficiary suits—non-negotiable terms, form contracts, incorporated obligations imposed by statute, and no statutory right to sue—all apply equally to the Medicaid Rebate Agreement. For this reason, it is not surprising that the Court frequently likened the 340B contract to the Medicaid Rebate Agreement.[9]

Third, a number of health care programs are implemented through form contracts. In addition to the 340B program, the Department of Veterans Affairs (VA) health care system, the Department of Defense (DOD) health care system (TRICARE), the Medicare Part D Coverage Gap Discount Program, and the Medicaid Drug Rebate Program are all implemented through non-negotiated form contracts that incorporate statutory duties. The Court's decision in *Santa Clara* should be instructive for any future third-party beneficiary suits under those agreements.

Fourth, the Court appropriately characterized the 340B contract as an "opt in" mechanism.[10] In other words, manufacturers would not have an obligation to comply with the statutory pricing requirements unless the manufacturer signed the contract. This "opt in" mechanism could be instructive in pending litigation involving the TRICARE retail pharmacy (TRRx) program operated by DOD. That program, which implements Section 703 of the 2008 Defense Authorization Act, 10 U.S.C. § 1074g, provides that the TRRx pharmacy network shall be treated as an "element of DOD" for purposes of the procurement of drugs under the Veterans HealthCare Act, 38 U.S.C. § 8126 (the VHCA). The VHCA, in turn, requires manufacturers to sign agreements, known as Master Agreements, that incorporate statutory requirements to charge prices no higher than a "federal ceiling price" for outpatient drugs procured by VA and DOD (among others). Pursuant to Section 703, DOD issued a regulation directing drug manufacturers to pay refunds on TRRx utilization designed to approximate the statutory pricing formula set forth in the VHCA for drugs procured directly by DOD.[11] That regulation is now being challenged as *ultra vires*.[12] Because the VHCA is implemented through form

6 *Id.* at 3.

7 *Id.*

8 *See*, e.g., *United States ex rel. Hixson* v. *Health Mgmt. Sys., Inc.*, 613 F.3d 1186, 1190 (8th Cir. 2010); *United States* v. *Southland Mgmt. Corp.*, 326 F.3d 669, 682 (5th Cir. 2003).

9 *See*, e.g., *id.* at 3, 6, 8.

10 *Id.* at 3.

11 74 Fed. Reg. 11,279, 11,286 (March 17, 2009).

12 *See, Coalition for Commonsense in Government Procurement* v. *United States*, 671 F. Supp. 2d 48 (D.D.C. 2009).

contracts that are similar in nature to the contract under the 340B program, the Supreme Court's recognition of the "opt in" requirement may support the plaintiffs' position that DOD's implementation of Section 703 through rulemaking, rather than through a contract mechanism, is improper.

Finally, the Supreme Court's decision reflects a continuing trend to reject private rights of actions under federal statutes unless Congress explicitly authorized private suits. Other statutes of significance to the pharmaceutical industry, including the Federal Food Drug & Cosmetic Act (FFDCA), similarly do not confer private rights of action. The Court's decision, and its reliance on cases rejecting implied private rights of action such as *Alexander* v. *Sandoval*,[13] may help to bolster arguments that private suits against pharmaceutical companies seeking damages resulting from alleged violations of the FFDCA are not authorized.

13 Slip op. at 6 (citing *Alexander* v. *Sandoval*, 532 U.S. 275, 286 (2001)).

Arnold & Porter LLP represented AstraZeneca and the other pharmaceutical manufacturer defendants in the briefing and argument at the Supreme Court, both at the certiorari and merits stages. If you have any questions regarding the issues covered in this Advisory, please contact your Arnold & Porter attorney or one of the following attorneys:

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