

### Where a Federal Statute Is Silent, Do Third-Party Beneficiaries of a Government Contract Have a Right to Sue?

#### CASE AT A GLANCE

Santa Clara County brought a class action in California federal court on behalf of public health care providers against a number of pharmaceutical companies, alleging that these companies violated the law by charging more than the ceiling price under the federal Public Health Service Act. The act imposes ceilings on the prices that drug manufacturers may charge for prescription medicines sold to specified health care facilities. As a condition for participating in Medicaid, drug manufacturers are required to enter into contracts with the Secretary of Health and Human Services to abide by the act's pricing restrictions. The Supreme Court must now consider whether so-called third-party beneficiaries of a government contract have a private right of action under the federal common law of contracts to enforce the act's pricing requirements, even though the federal statute contains no express or implied right of action to sue.

***Astra USA, Inc. v. County of Santa Clara, CA***  
**Docket No. 09-1273**

**Argument Date: January 19, 2011**  
**From: The Ninth Circuit**

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#### ISSUE

Whether federal courts may confer a private right to sue for breach of contract on third-party beneficiaries of a government contract, pursuant to federal common law, when the statute mandating the contract contains no express or implied right of action?

#### FACTS

This appeal by the *Astra* pharmaceutical defendants is grounded in a complicated federal statutory scheme and as such, the litigation is littered with an alphabet soup of statutory references and acronyms. In essence, this litigation centers on the problem of whether Santa Clara County, California, on behalf of a large number of California public health facilities, can bring a suit against pharmaceutical companies for overpricing the cost of their drugs sold to these facilities, in violation of law. Simply, the health facilities contend that they have a federal common-law right to sue for breach of contract. In contrast, the pharmaceutical companies contend that the federal statutory scheme governing drug pricing confers no express or private right of action on these "third-party" beneficiaries of a government contract.

The basis for this litigation is two interrelated and complex federal statutes, the Public Health Service Act and the Medicaid Rebate Act. Provisions of these statutes impose drug-pricing regulations on drug manufacturers whose drugs are covered by Medicaid. Provisions of the Public Health Service Act impose ceilings on the prices that drug manufacturers may charge for prescription medicines that are sold to specified health care facilities and entities. These facilities are referred to as 340B entities. See 42 U.S.C. § 256b. These entities

include public hospitals and community health centers, many of which provide safety-net services to the poor. Approximately 14,500 entities across the United States participate in this program as 340B entities.

The Public Health Service Act and the Medicaid Rebate Act, as a condition of participating in state Medicaid programs, require drug manufacturers to enter into contracts with the Secretary of Health and Human Services. Under these contracts, the drug manufacturers agree to adhere to the acts' pricing restrictions. Ceiling prices for a particular drug are determined based on the manufacturer's "average manufacturing price" and "best price" prescribed and defined by the Medicaid Rebate Act. The drug companies have reporting duties regarding these parameters for setting a ceiling price for a drug.

The contracts that pharmaceutical companies enter into with the Secretary are known as Pharmaceutical Pricing Agreements (PPAs). Under the PPAs, the drug manufacturers agree to provide discounted prices to the 340B health care providers and entities. Approximately 550 drug manufacturers have entered into PPAs with the Secretary, covering more than 35,000 drugs.

The Medicaid Rebate Act contains several provisions authorizing the Secretary of Health and Human Services to enforce the drug-pricing requirements. The Secretary may survey wholesalers and manufacturers to verify manufacturer prices. The Secretary may also suspend agreements and impose \$1,000 a day penalties for companies who fail to report their "average manufacturing price" or "best price" on a timely basis. Manufacturers are subject to civil monetary penalties

of up to \$100,000 for providing false information. The Secretary may terminate an agreement for violation of the agreement, or other good cause.

If the Secretary believes that a manufacturer is not complying with the requirements, the PPA authorizes the Secretary to initiate an informal dispute resolution process. The PPA specifies that the agreement shall be construed in accordance with federal common law, but it contains no provision that allows a 340B entity, or any third-party beneficiary of the agreement, to enforce the terms of the pricing agreement.

Despite the PPA agreements, many drug manufacturers have in the past overcharged 340B health facilities for their drugs, through various fraudulent schemes which have come to light as a consequence of whistle-blower complaints. As a consequence of these suits, a number of drug companies have paid out large sums of money in settlement of claims, although only a small portion of settlement dollars have reimbursed 340B entities that overpaid the drug manufacturers.

Apart from the fraud litigation, federal administrative enforcement efforts have been lax; the federal regulatory apparatus for policing violations of the drug manufacturers' best-price duties has been hampered by staffing and budgetary constraints.

Against this backdrop, this litigation concerning violation of the drug pricing agreements has followed a somewhat complicated path through the California courts. Originally, Santa Clara County (the County), on behalf of numerous 340B health care facilities in California, brought a class action lawsuit in California state court, alleging that various pharmaceutical companies were overcharging for drugs sold to the facilities. From 2003 to 2005, Santa Clara County's 340B entities spent approximately \$90 million on drugs sold under the agreement with drug manufacturers.

The drug companies removed the litigation to the federal court for the Northern District of California. After removal, the County amended its complaint to add a third-party beneficiary breach of contract claim, on behalf of the 340B health facilities, alleging that the pharmaceutical companies were overcharging the health care facilities under the 340B program, in violation of the PPAs.

In an unreported decision, the federal district court dismissed all the state claims, including the third-party beneficiary breach of contract claim. The court held that the 340B entities were intended third-party beneficiaries under the PPA. However, the court held that neither the statute nor the pricing agreement reflected an intent to provide private parties the right to sue to enforce the pricing requirements.

On appeal, the Ninth Circuit reversed and held that federal common law provides a third-party beneficiary, such as a 340B health care facility, with a breach of contract action to enforce the act's drug pricing provisions, as incorporated into the agreements. See 540 F.3d 194 (9th Cir. 2018). The court held that allowing such suits was consistent with congressional intent, even though the statute itself did not create a federal private right of action. The Ninth Circuit disagreed with the district court's conclusion that something more was needed to allow 340B entities to sue to enforce the pricing agreement.

The Ninth Circuit's decision led to a discovery dispute on remand to the district court concerning the scope and nature of pricing information and underlying data that the drug companies would be obliged to supply to the plaintiffs. When the district court limited discovery, the plaintiffs sought interlocutory appeal to the Ninth Circuit. At this point, the Ninth Circuit invited the Secretary of Health and Human Services to file an amicus brief. In response, the United States government expressed that "it never imagined that a 340B entity could bring a third-party beneficiary lawsuit" and that such a lawsuit would confer "rights never intended" by the pricing agreements. The United States also indicated that permitting a private right of action would be disruptive to the statutory pricing and enforcement schemes.

The Ninth Circuit then issued a superseding decision that reissued its earlier decision, but struck the restrictive language relating to the scope of permissible discovery. This superseding decision did not discuss or defer to the Secretary's conclusion that permitting a private right of action would be disruptive to the statutory scheme. 588 F.3d 1237 (9th Cir. 2019).

## CASE ANALYSIS

There is a considerable body of well-established case law that suggests that private individuals have no right to bring a lawsuit to enforce provisions of a federal statutory scheme, in absence of the statute expressly or implicitly providing a private right of action. In absence of such an express or implied right of action, an individual citizen either has no right to pursue relief or must rely on other officers or agents to provide enforcement of statutory provisions.

Discerning whether a statutory scheme provides for an *express* right of action is a usually a straightforward affair: Congress expressly indicates such a right of action in the statutory language. On the other hand, much of the litigation concerning who has a right to enforce federal statutory provisions has centered on the concept of an implied right of action. The problem of an *implied* right of action arises when a statutory scheme does not, by express language, confer a right to sue on private individuals or entities, but such a right may be implied from the statutory context, statutory construction, or legislative intent.

The Supreme Court's receptivity to the notion of implied rights of action has varied over time. During the heyday of the liberal Warren Court era, the doctrine of implied rights of action was particularly used to enforce alleged violations of federal civil rights was viewed favorably by the Court. See *J.I. Case v. Borak*, 377 U.S. 426 (1964). In that era, the Court set forth various tests to determine whether a federal court might imply a right of action through statutory construction and legislative intent. In more recent times, however, the concept of implied rights of action has fallen into disfavor, with conservative justices on the Court, especially Justice Scalia, inveighing against any concept of implied rights of action. See *Corr. Serv. Corp. v. Malesko*, 534 U.S. 61 (2001); *Alexander v. Sandoval*, 532 U.S. 275 (2001).

In this litigation, the County has conceded that the Public Health Service Act does not confer a private right or remedy on the 340B health care facilities. The pharmaceutical company defendants have framed the core issue as an attempt by the County, on behalf of the 340B health care facilities, to read an implied right of action in the Public Health Service and Medicaid Rebate Acts. Simply, the pharmaceutical

companies contend that by allowing a private plaintiff (in this case, the third-party health care facilities) to bring a federal common-law contract claim based on a federal statute that does not provide for a private right of action “contravenes congressional intent and decades of the Court’s private right of action jurisprudence.”

The pharmaceutical companies contend that unless Congress intends to create a private right of action, a cause of action does not exist and the courts may not create one. Thus, Congress must create a private right of action to enforce a federal statute. As a corollary, a purported beneficiary of a federal statute is not entitled to enforce a statutory obligation simply because Congress mandated that the obligation be incorporated into a government contract.

Thus, the focus of the inquiry, according to the pharmaceutical companies, must be on whether Congress intended to provide a private remedy. Because Congress chose not to create an express or implied private cause of action to allow the 340B health care facilities to enforce the statutes’ pricing provisions through damage suits, the federal courts cannot, through invocation of the federal common law of contract, create such a right. And, where no private right of action exists under a relevant statute, a plaintiff’s efforts to bring a common-law claim present an impermissible end run around the statute, conclude the pharmaceutical companies.

Moreover, the pharmaceutical companies contend that permitting the private enforcement of the pricing requirements by 340B health care facilities would seriously interfere with the administration of the statutory scheme and its various enforcement mechanisms. The companies particularly claim that allowing private lawsuits would interfere with the judgments of the Secretary of Health and Human Services with regard to ceiling pricing. The defendants contend that oversight of drug pricing mechanisms should be left to the Secretary of Health and Human Services, and not to private plaintiffs, whose interests “inevitably” will diverge from those of the government’s. Private suits, claim the defendants, also would conflict with Congress’s decision to vest enforcement in the Secretary of Health and Human Services.

Moreover, the pharmaceutical companies argue that allowing private rights of action to enforce contractual obligations would impose unwarranted and costly administrative burdens on drug manufacturers, particularly relating to civil litigation discovery expenses. In support of this argument, the defendants point to the costs and burdens of discovery production that the pharmaceutical companies already have incurred in the underlying litigation, prior to the district court issuing a stay of discovery pending the Supreme Court litigation.

While the pharmaceutical companies argue that the litigation presents a straightforward question of implied rights of action, the County instead maintains that the litigation does not seek to enforce the Public Health Service Act, but rather the pricing contract agreements between the Secretary of Health and Human Services and the drug manufacturers. The pricing agreements are enforceable contracts. In selecting contracts as a mechanism to implement the Medicaid drug pricing program that would benefit the 340B health facilities, Congress indicated no intent to depart from ordinary contract principles. In this view, the County claims, as third-party beneficiaries, the 340B health care facilities have the right to sue to enforce contract provisions of which they are an intended beneficiary.

Hence in the County’s view, the right to sue is derivative of the fact that the 340B health facilities are a third-party contract beneficiary and has no relationship to whether the Public Health Act expressly or impliedly confers a right to sue on these entities. In other words, the County contends that this litigation is not about whether the health care facilities have an implied right of action under the public Health Service Act, and that the defendants arguments relying on implied right of action jurisprudence are misplaced.

The thrust of the County’s argument focuses on the contractual nature of the relationship between the Secretary and the pharmaceutical companies, the 340B health care facilities as third-party beneficiaries of the PPAs. From this relationship flows the contractual obligation of the pharmaceutical companies to comply with drug pricing requirements. Thus, much of the County’s argument is devoted to establishing that the 340B health care facilities are third-party contract beneficiaries, and as such, have a common-law right to sue for breach of contract. Both the district court and the Ninth Circuit found that the 340B health care facilities are third-party beneficiaries. And, at great length, the plaintiffs point out that the principle that contracts may be enforced by a class of third-party beneficiaries has been established at common law since the 1600s.

The fundamental principle invoked by the plaintiffs, then, centers on the rule that when Congress statutorily directs the making of a contract, then Congress expects the agreement, like ordinary contracts, to be enforceable by a private lawsuit for breach of contract. The plaintiffs contend that this litigation is not about implying a right of action in a federal statute, but rather a private right of action derived from a contractual relationship. Hence, the plaintiffs repeatedly invoke the quotation that cases involving federal contracts “do[ ] not fit comfortably in th[e] mold of private right of action cases.” *Jackson Transit Auth. v. Local Div. 1285*, 457 U.S. 15 (1982).

Furthermore, the County argues that the breach of contract remedy advances the congressional intent to provide 340B health facilities, which largely serve the poor, with the best drug prices. Thus, the availability of private litigation complements and is fully compatible with federal government enforcement efforts, which have been weak and insufficient to ensure fair drug pricing. The plaintiffs contend that the Department of Health and Human Services is ill-equipped to enforce the statutory best-price requirement and that the Department, even when presented with solid evidence of violations, has often failed to remedy those violations. In addition, waiting for whistleblower lawsuits is not a reliable means of enforcing the statutory pricing requirements.

In response, the pharmaceutical companies argue that a plaintiff may not circumvent congressional intent not to confer a right of action, merely by artful pleading of the expedient of putting a different label on its cause of action. The defendants contend that the County basically has “dressed up an implied right of action claim in breach-of-contract clothes.” In other words, the defendants contend that the health care providers cannot create a private right of action simply by characterizing the litigation as a common-law breach of contract case, of which they are a third-party beneficiary. According to the defendants, where plaintiffs have attempted to artfully circumvent congressional intent by asserting contract-based claims to enforce federal statutes, courts have held that congressional intent controls.

The pharmaceutical companies argue that rather than deriving from contract law, the substantive right that the plaintiffs seek to enforce (redress for alleged drug overpricing) derives from an act of Congress. Hence, a private right of action by third-parties to enforce a contract's ceiling price obligations is indistinguishable from a private right of action to enforce the statutory ceiling price obligation set forth in the contract. Consequently, the defendants contend that the Ninth Circuit "invented" a right to sue under the federal common law of contract. The creation of such a right conflicts with the requirement that only Congress can authorize private enforcement of the Public Health Service Act.

## SIGNIFICANCE

How the Supreme Court resolves *Astra* will largely turn on which characterization of the litigation the Court endorses. If, as the defendants argue, the Court views this appeal as involving a statutory implied-right-of-action case, then the Court's deliberations may be brief, given the predisposition of the Court to disfavor implied rights of action. However, if, as the County suggests, the case instead involves the rights of a third-party beneficiary to sue for breach of contract, then the Court's problem is more complex. At the outset, the Court is faced with the task of properly characterizing the issue at stake.

Another possible outcome is that the Supreme Court may determine, after briefing and argument, that the Court improvidently granted certiorari. Here, the Court's task is further complicated by the presence of the United States as an amicus on behalf of the petitioner. The government has distanced itself from and rejected the respondents' reliance on the implied-right-of-action theory of the case. Instead, the government points to the March 2010 enactment of the Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119, which made significant changes to the 340B program. Among several changes, this new legislation directs the Department of Health and Human Services to institute a comprehensive administrative process to adjudicate and remedy violations of the pricing requirements. This legislation applies to drug purchases after January 1, 2010. In the government's view, these new statutory provisions provide the exclusive remedy for 340B entity claims that they have been overcharged. The United States contends that this statutory enactment will preclude future third-party breach-of-contract claims presented in this case.

The County has aptly pointed out that if the United States is correct that the remedy the Department of Health and Human Services has created for sales after January 1, 2010, is exclusive, then this severely limits the importance of the question presented and arguably warrants the Court to dismiss the certiorari petition as improvidently granted. However, the County points out that whether the new amendments will preclude future breach-of-contract claims is not presented to the Court, nor do the amendments apply to overpricing claims before January 2010.

Finally, the usual array of amici representing business interests, such as the United States Chamber of Commerce and the Washington Legal Foundation, have aligned to support the defendants, noting that the federal government enters into millions of contracts pursuant to statutory authorization. They contend that to uphold a finding of a third-party beneficiary's common-law right to sue, without express statutory authority, would compromise the certainty of contracts and undermine business relationships with the government.

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*PREVIEW of United States Supreme Court Cases*, pages 170–173.  
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