No. 09-1273

IN THE

Supreme Court of the United States

ASTRA USA, INC.; ASTRAZENECA PHARMACEUTICALS LP; AVENTIS PHARMACEUTICALS, INC.; BAYER CORP.; BRISTOL-MYERS SQUIBB CO.; PFIZER, INC.; SCHERING-PLOUGH CORP.; SMITHKLINE BEECHAM CORP.; TAP PHARMACEUTICAL PRODUCTS, INC.; WYETH, INC.; WYETH PHARMACEUTICALS, INC.; ZENECA INC.; ZLB BEHRING LLC.

Petitioners,

v.

COUNTY OF SANTA CLARA, ON BEHALF OF ITSELF AND ALL OTHERS SIMILARLY SITUATED,

Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

REPLY BRIEF

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PETITIONERS' REPLY BRIEF

Although Congress did not authorize a private right to enforce the drug pricing provisions of the 340B Act and the Medicaid Drug Rebate Program, the Ninth Circuit created such a right anyway. But only Congress can create a cause of action to enforce a statute. The Ninth Circuit's abuse of judicial power under the guise of federal common law warrants this Court's correction.

The decision also deepens a mature and intractable circuit conflict on whether a private plaintiff may sue under the common law as a third-party beneficiary of a government contract that incorporates a requirement of a federal statute, where the statute itself does not confer a private right of action. The question whether a statute may be enforced by a common law claim arises frequently and is of paramount importance. Billions of federal dollars are administered through government contracts that incorporate statutory requirements that Congress arguably enacted for the benefit of third parties. Few questions could be more worthy of this Court's attention than whether federal courts may authorize a private right of action when Congress concededly did not.

If left uncorrected, the decision would disrupt the 340B Act and Medicaid Drug Rebate Programs and would upend Congress's considered judgment to vest the Secretary of HHS with exclusive enforcement of those programs. Those programs are massive in size, scope, and technical complexity. The court of appeals' decision subjects an entire industry of drug manufacturers to an onslaught of private challenges with respect to every pricing calculation under the 340B Act for thousands of drugs worth billions of dollars. Those calculations are exceedingly

complicated and technical, and the pricing methodology requires a multitude of policy decisions that Congress intended the Secretary to make and implement on a uniform and centralized basis.

The decision below displaces the congressional framework with class action lawsuits that seek to impose massive liability and unjustified and extraordinary burdens on drug manufacturers. The court of appeals disrupted the statutory scheme without so much as remarking on the Secretary's view that a private right of action would disrupt her ability to administer the 340B Program as well as the vastly larger Medicaid Rebate Program whose drug pricing provisions are incorporated into the 340B Act. It is bad enough that the court invented a cause of action over Congress's refusal to create one. But the court did so also over the express objection of the two parties to PPAs, including the agency charged with administering the statute.

A. The Conflict in the Circuits Warrants This Court's Review

1. There is a firmly entrenched circuit conflict on the question whether the federal common law provides a basis for a third-party beneficiary contract claim to enforce a statutory requirement embodied in a government contract when Congress has not authorized a private right of action to enforce the statute. Pet. 13-17. Respondents respond by asserting that the question whether a statute confers a private right of action is distinct from the question whether a third-party beneficiary can bring a common law claim under a contract that incorporates the statute. Br. in Opp. 21-23. That question, however, is precisely the issue over which the circuits are deeply divided.

Three circuits have rejected respondents' contention, holding that the absence of a statutory

right of action categorically precludes pleading the same right to sue under the guise of a common law contract claim. *Grochowski v. Phoenix Constr.*, 318 F.3d 80 (2d Cir. 2003); *Hodges v. Atchison, Topeka & Santa Fe Ry. Co.*, 728 F.2d 414 (10th Cir. 1984); *Hoopes v. Equifax, Inc.*, 611 F.2d 134 (6th Cir. 1979). Thus, the Tenth Circuit held that "a third-party beneficiary" theory is "another aspect of the implied right of action argument." *Hodges*, 728 F.2d at 416. The Second Circuit likewise held that "common law claims are clearly an impermissible 'end run'" around Congress's decision not to provide for private enforcement of a statutory requirement. *Grochowski*, 318 F.3d at 86. And the Sixth Circuit in *Hoopes* similarly dismissed the common law claim because the statute at issue "does not authorize a private cause of action." 611 F.2d at 135.

Those decisions squarely conflict with the five circuits that have held that a common law contract claim may proceed notwithstanding the absence of a statutory right to sue. Pet. 16-17. Indeed, the Seventh Circuit in *D'Amato v. Wisconsin Gas Co.,* 760 F.2d 1474, 1478 n.4 (1985), explicitly criticized the Sixth Circuit's decision in *Hoopes* for "failing to distinguish between [a] third-party beneficiary claim and a private cause of action."

Respondents argue that none of those decisions in the five circuits "is an implied right of action case." Br. in Opp. 26. That is incorrect. Each decision involved a purported third-party beneficiary that sought to enforce a statutory requirement embodied in a contract; each decision recognized that the statute conferred no right of action; and each decision nonetheless considered whether the plaintiff met the common law elements of a third-party beneficiary. *Dewakuku v. Martinez*, 271 F.3d 1031, 1040-42 (Fed. Cir. 2001); *D'Amato*, 760 F.2d at 1478-82; *Nguyen v. U.S. Catholic Conference*, 719 F.2d 52, 55-56 (3d Cir.

1983); *Perry v. Housing Auth. of Charleston*, 664 F.2d 1210, 1218 (4th Cir. 1981); *Falzarano v. United States*, 607 F.2d 506, 511 (1st Cir. 1979). Those decisions squarely conflict with the three circuits that categorically foreclose common law claims to enforce a statute.

Respondents similarly err in suggesting that the Second, Sixth, and Tenth Circuits precluded contract claims only because the statutes at issue contained administrative remedies. Br. in Opp. 23-25. The Second and Tenth Circuits mentioned the presence of administrative remedies only in holding that Congress declined to confer a private right of action. *Grochowski*, 318 F.3d at 85; *Hodges*, 728 F.2d at 416. The presence of administrative remedies thus was irrelevant to those courts' refusal to entertain contract claims under the common law; the absence of a private right of action alone was dispositive. *Grochowski*, 318 F.3d at 86; *Hodges*, 728 F.2d at 416; *see* Pet. 19-20. Respondents thus seriously err in relying on the absence of administrative remedies under the 340B Act. Indeed, that absence makes the court of appeals' invention of a damages action all the more egregious because Congress plainly foreclosed *all* private remedies.

In any event, respondents are mistaken in limiting the Ninth Circuit's decision to statutes that lack administrative remedies. The court indicated that the common law provides a claim whenever one would benefit the plaintiff in light of the overall purposes of the statute. The court observed that a plaintiff's "right to sue inheres in one's status as an intended beneficiary," Pet. App. 39a, and further stated that "[f]ederal common law contract remedies are one way of ensuring that drug companies comply with their obligations under the program and provide [the] discounts" required by the statute, *id.* at 55a.

2. Respondents argue that, under common law contract principles, 340B entities are third-party beneficiaries under the PPAs between the Secretary and the pharmaceutical companies. Br. in Opp. 21, 25-26, 28, 31-33. That conclusion only highlights that the conflict in the circuits is squarely presented here.

Respondents' presumed status as third-party beneficiaries under common law principles is controlling in the five circuits that allow common law claims to enforce statutory requirements. But that status is irrelevant in the three circuits that categorically preclude such claims. The issue that has divided the circuits is therefore dispositive in this case, and only this Court can resolve the deep division among the courts of appeals.

3. This case is an ideal vehicle to resolve an issue of immense importance that has deeply and long divided the courts of appeals. As respondents observe, none of the circuits that have considered a federal common law claim have held that the plaintiff met the common law elements. Br. in Opp. 26-27. That is hardly surprising. Where Congress has not conferred a private right of action, a plaintiff faces an uphill battle in showing that the contracting parties intended to create a private right of action despite Congress's contrary judgment. *See* Chamber of Commerce Am. Br. 6.

Yet here the Ninth Circuit affirmatively created a cause of action that Congress itself declined to authorize. Pet. App. 36a. This case demonstrates how far from the mainstream the Ninth Circuit has strayed and underscores the need for the Court to resolve the split of authority over the question of whether federal courts may recognize common law claims to enforce a statute.

4. Respondents make no attempt to dispute that the question presented is of recurring importance and affects a wide swath of federal programs. In the health care field alone, numerous statutes are implemented through contracts that are similar to PPAs and drug rebate agreements. Pet. 19. Moreover, U.S. companies annually enter into billions of dollars worth of contracts that incorporate obligations set forth by statutes, executive orders, and regulations. Chamber of Commerce Am. Br. 14-15.

The Ninth Circuit's decision covers the largest population of any circuit. *See* U.S. Census Bureau, *Statistical Abstract of the United States* (2010), Table 12 (60 million persons). If not immediately corrected by this Court, the court of appeals' decision opens the door for countless "intended beneficiaries" of federal programs administered by contract to sue to enforce statutory requirements that Congress never intended to subject to private enforcement. And the mere presence of the conflict continues to generate litigation, uncertainty, and disruption to federal programs administered though contracts. Pet. 21-24; Chamber of Commerce Am. Br. 12-16.

B. The Ninth Circuit's Decision Disrupts the 340B and Medicaid Drug Rebate Programs

1. Respondents do not dispute that the Ninth Circuit's decision has the immediate impact of permitting thousands of 340B entities to bring private actions for damages. Pet. 21-22. Respondents also do not dispute that, because drug manufacturers' drug pricing obligations under the 340B Program are borrowed from the Medicaid Drug Rebate Program, their suit calls into question the same pricing decisions under the rebate program. Pet. 22-23.

The impact of the Ninth Circuit's decision on both programs is staggering both in size and scope. Total Medicaid drug rebates to States and 340B discounts to covered entities approach $10 billion *annually*. PhRMA Am. Br. 16 & n.4; Pet. 21-22. Drug manufacturers must, monthly and quarterly, calculate and report AMP for over 25,000 products, and manufacturers must quarterly calculate and report BP for more than 6,300 drug products. PhRMA Am. Br. 16. Those calculations are not dictated by simple mathematical formulas. Quite to the contrary, a variety of complex and technical issues of pricing methodology must be resolved before manufacturers can calculate and report AMP and BP to the Secretary, and the Secretary in turn has given drug manufacturers considerable discretion to resolve open questions of pricing methodology. Pet. 24-25; PhRMA Am. Br. 13-20.

Given that Congress concededly conferred no private right of enforcement, the Ninth Circuit's recognition of a right to sue an entire industry warrants this Court's review. Given the sheer size, scope, and complexity of the 340B Program and the Medicaid Rebate Program, the Ninth Circuit should not have the last word on whether drug manufacturers may be exposed to massive unanticipated claims and varying and possibly conflicting obligations as courts sort through what is the "correct" AMP or BP.

2. The Ninth Circuit did not address the government's view that it "never imagined that a 340B entity could bring a third-party beneficiary lawsuit" and that such suits confer "rights never intended by the PPA signatories." Brief of the United States of America as Amicus Curiae in Support of the Judgment Below, *County of Santa Clara v. AstraZeneca Pharm. LP*, No. 09-15216, 2009 WL 4089524, at *9, *12 (9th Cir. Oct. 27, 2009)

("Gov't Br."); Pet. 24-26, 33. The court thus ignored the Secretary's judgment that private suits would "threaten the orderly operation of *both*" the Medicaid drug rebate and 340B programs by "undermin[ing]" HHS's supervision of both programs. Gov't Br., 2009 WL 4089524, at *9, *11. The Ninth Circuit's disregard of the Secretary's view warrants this Court's correction.

Respondents remark that their suit produces a "win-win" under the Medicaid drug rebate and 340B programs because a lower BP generally benefits States as well as 340B entities. Br. in Opp. 34. That observation ignores and does not refute the government's view that States and 340B entities have conflicting incentives with respect to *AMP*. Gov't Br., 2009 WL 4089524, at *15; *see* Pet. 25-26; PhRMA Am. Br. 21. Thus, manufacturers are placed in the untenable position of being exposed to conflicting AMP obligations depending on the identity of the plaintiff. Even with respect to BP, private suits expose manufacturers to case-by-case determinations of the correct BP, where Congress left that determination exclusively to the Secretary to make on a uniform, nationwide basis.

3. Respondents rely on the government's view below that this case would not implicate the Secretary's primary jurisdiction under certain circumstances. Br. in Opp. 20, 33-34. The government advised the Ninth Circuit that respondents, in theory, could limit their suit to allegations of mechanical error or outright fraud, without contesting the drug manufacturers' underlying AMP and BP pricing methodology and calculations, *i.e.*, those areas in which private suits would seriously interfere with HHS's enforcement of both programs. Gov't Br., 2009 WL 4089524, at *13-*14.

After the government filed its brief, however, the Ninth Circuit's superseding opinion deleted the prior language that suggested the suit was limited to reported prices. Pet 12; *see* Pet. App. 65a-66a. On remand respondents challenged and sought massive discovery with respect to well over a hundred million records relating to intricate and confidential pricing methodology, thus implicating the very concerns leading the Secretary to conclude that private suits are incompatible with congressional intent and her exclusive enforcement of both programs. Pet. 23-24.

C. The Ninth Circuit's Decision Is Manifestly Wrong

1. Respondents concede that the 340B Act contains no private right of action and confers no private remedies to enforce the drug pricing requirements. Br. in Opp. 3-4. That should have been the end of the matter. This Court has long since abandoned a general federal common law, and our constitutional structure permits only Congress to permit private enforcement of legislative enactments. Pet. 26-33. The Ninth Circuit's holding flagrantly disregards this Court's recent implied right of action jurisprudence, Pet. 31-32, and turns that jurisprudence on its head by holding that the federal common law of contracts "ordinarily" provides a cause of action that Congress must "*abrogate*." Pet. App. 24a n.16 (emphasis added); *accord* Br. in Opp. 28 ("[T]he County's contract claim is not displaced by the statute.").

A common law claim renders the absence of an implied right of action meaningless since the substantive right to enforce the requirement is the same under either doctrine. Respondents do not

argue to the contrary. This Court's Spending Clause jurisprudence moreover requires that Congress speak with a clear voice before authorizing a private suit against a party that "contracts" with the government under Spending Clause legislation. Pet. 32-33. *A fortiori*, courts lack the power on their own to impose unanticipated liabilities on contractors.

This Court's decision in *United States v. Erika, Inc.*, 456 U.S. 201, 206-211 (1982), rejects the notion that a plaintiff can circumvent the absence of a private right of action by alleging that it is a third-party beneficiary to a government contract. Pet. 28-30. Contrary to respondents' assertion, Br. in Opp. 29-31, *Erika*'s rejection of the contract claim was not based on the presence of administrative remedies. Rather, the Court explained that its task was "at an end" upon concluding that Congress intended to withhold a judicial remedy. 456 U.S. at 211. Indeed, because this Court's decisions squarely foreclose the holding below and because the Ninth Circuit is the only circuit court to have upheld a common law claim to enforce a statute, this Court may wish to consider summary reversal.

Respondents err in relying (Br. in Opp. 4-5) on *Jackson Transit Authority v. Local Division 1285*, 457 U.S. 15 (1982), and *Clearfield Trust Co. v. United States*, 318 U.S. 363 (1943). Those decisions addressed whether federal or state law governed a contract claim. *Cf. Boyle v. United Techs. Corp.*, 487 U.S. 500 (1988) (tort action). *Jackson Transit* also is inapposite because the plaintiff was a party to the contract, and the Court held that Congress intended that the contract be enforceable, albeit under state

law. 457 U.S. at 21 ("[T]he precise question before us is whether the union's contract actions are federal causes of action, not whether the union can bring suit at all to enforce its contracts."). Similarly, *congressional intent* controls the scope of the cause of action. *Id.*; *see also Empire Healthchoice Assurance, Inc. v. McVeigh*, 547 U.S. 677, 694-695 (2006). No decision of this Court supports the proposition that where Congress declines to create a cause of action, a court may create one anyway.[1]

CONCLUSION

For the foregoing reasons and those stated in the petition for a writ of certiorari, the petition should be granted or the decision summarily reversed.

Respectfully submitted,

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[1] Respondents cite inapposite decisions that do not involve a federal statute, Br. in Opp. 4 (citing *Robins Dry Dock & Repair Co. v. Flint*, 275 U.S. 303 (1927), and *German Alliance Ins. Co. v. Home Water Supply Co.*, 226 U.S. 220 (1912)), and decisions involving suits by or against the United States, *id.* at 5 (citing *United States v. Little Lake Misere Land Co.*, 412 U.S. 580 (1973), and *United States v. Kimbell Foods, Inc.*, 440 U.S. 715 (1979)).

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