No. 09-1273

IN THE

Supreme Court of the United States

ASTRA USA, INC., *et al.*,
Petitioners,

v.

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

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

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QUESTION PRESENTED

Section 340B of the Public Health Service Act, 42 U.S.C. § 256b, imposes ceilings on the prices that drug manufacturers may charge for prescription medicines sold to specified health care facilities and entities, known as 340B entities. Section 340B implements the ceiling prices by requiring the Secretary of Health and Human Services to enter into contracts setting forth the Act's pricing restrictions, and drug manufacturers are required to enter into those contracts as a condition of participation in Medicaid. 42 U.S.C. §§ 1396b(i)(10), 1396r-8(a)(1), (5).

In the decision below, the Ninth Circuit held that covered 340B entities have a private right of action under "federal common law" to enforce the Act's pricing requirements, even though the Act itself contains no express or implied private right of action. The Ninth Circuit held that a plaintiff may pursue a federal common law claim as a third-party beneficiary of a contract that embodies statutory requirements.

The question presented is whether, in the absence of a private right of action to enforce a statute, federal courts have the federal common law authority to confer a private right of action on non-parties to the contract simply because the statutory requirement sought to be enforced is embodied in the contract.

PARTIES TO THE PROCEEDING

Petitioners Astra USA, Inc., AstraZeneca Pharmaceuticals LP, Aventis Pharmaceuticals Inc., Bayer Corp., Bristol-Myers Squibb Co., Pfizer Inc., Merck & Co., Inc. (f/d/b/a Schering-Plough Corp.), SmithKline Beecham Corp. (d/b/a GlaxoSmithKline), TAP Pharmaceutical Products Inc. (n/k/a Takeda Pharmaceuticals North America, Inc.), Wyeth, Inc., Wyeth Pharmaceuticals, Inc., Zeneca Inc., and ZLB Behring LLC were defendants in the district court and appellees in the court of appeals.

Respondent County of Santa Clara was the plaintiff in the district court and appellant in the court of appeals.

RULE 29.6 STATEMENT OF CORPORATE DISCLOSURE

The corporate disclosure statement included in the petition for a writ of certiorari remains accurate.

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BRIEF FOR THE PETITIONERS

OPINIONS BELOW

The decision of the court of appeals is reported at 588 F.3d 1237. Pet. App. 1a-29a. The previous opinion of the court of appeals is reported at 540 F.3d 1094. Pet. App. 30a-58a. The unreported district court decisions reviewed by the court of appeals are set forth at Pet. App. 79a-96a and 97a-124a.

JURISDICTION

The court of appeals entered its decision on December 9, 2009. Pet. App. 1a. A petition for rehearing was denied on February 11, 2010. Pet. App. 125a. The petition for a writ of certiorari was

filed on April 21, 2010, and granted on September 28, 2010. This Court has jurisdiction under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

The relevant provisions of Section 340B of the Public Health Service Act, 42 U.S.C. § 256b, and Section 1927 of Title XIX of the Social Security Act, 42 U.S.C. § 1396r-8, are set forth at Pet. App. 127a-164a.

STATEMENT

This case presents the question whether a private plaintiff may sue as a third-party beneficiary of a government contract that incorporates the requirements of a federal statute that does not confer a private right to sue. The issue here arises under two inextricably interrelated and complex federal statutes—the Medicaid Rebate Act ("Medicaid Act") and Section 340B of the Public Health Service Act ("340B Act")—that impose drug-pricing obligations on drug manufacturers whose outpatient drugs are covered by Medicaid. Those statutory drug-pricing requirements can be enforced by the Secretary of Health and Human Services ("the Secretary"), but there is no provision—express or implied—for enforcement by private parties.

The Medicaid Act requires all drug manufacturers whose outpatient drugs are covered by Medicaid to enter into contracts with the Secretary. Those agreements are known as Medicaid Rebate Agreements, and under them the manufacturers agree to provide drug rebates to States. The Medicaid Act also requires the same drug manufacturers to enter into a separate contract with the Secretary, known as the Pharmaceutical Pricing Agreement ("PPA"),

pursuant to the 340B Act, 42 U.S.C. § 256b. *See* 42 U.S.C. § 1396r-8(a)(1), (5). Under the PPA, manufacturers agree to provide deeply discounted prices to certain health care providers and entities, *id.* § 256b(a), referred to as "340B entities."

The Medicaid Act specifies the formula for calculating rebates owed to States under the Medicaid program, and the 340B Act specifies the formula for calculating the ceiling prices that apply to purchases by 340B entities. Both the Medicaid rebate amounts and the Section 340B ceiling prices for a particular drug are based on the drug manufacturers' Average Manufacturer Price ("AMP") and Best Price ("BP") as prescribed and defined by the Medicaid Act. *Id.* §§ 256b(a), 1396r-8(c).

Congress specified that the manufacturers' obligations to calculate and report AMP and BP "shall" be incorporated into both the Medicaid Rebate Agreements and the PPA. *Id*. §§ 256b(a)(1), 1396r-8(b)(3)(A). The Medicaid Act thus mandates that Medicaid Rebate Agreements require drug manufacturers to calculate and report AMPs and BPs to the Secretary for Medicaid covered drugs. *Id*. § 1396r-8(b)(3)(A). The 340B Act similarly specifies that the PPA must require drug manufacturers to use their AMP and BP as defined in, and as regulated by the Secretary under, the Medicaid Act to calculate the ceiling price for Section 340B drugs. *Id*. § 256b(a)(1), (2).

In the decision below, the Ninth Circuit held that federal common law confers on 340B entities the right to sue to enforce the statutory requirement that drug manufacturers accurately calculate and report to the Secretary the AMP and BP for all Medicaid covered drugs and ceiling prices for all Section 340B

drugs, *even though the 340B Act itself concededly confers no private right of action to sue*. The court of appeals reasoned that, although there is no express or implied right of action to enforce the statutory drug price calculation and reporting requirements under the statute, 340B entities have a federal common law claim for breach of contract as third-party beneficiaries of the PPA between drug manufacturers and the Secretary under the 340B Act.

The Ninth Circuit thereby created under the federal common law the right to enforce the 340B Act's drug-pricing provisions where the statute itself confers no such right. Pet. App. 3a, 8a, 29a. This Court's jurisprudence forecloses the Ninth Circuit's creation of a private right of action. A suit to enforce the contract term incorporating the statutory pricing obligation asserts the same substantive right—the right to the 340B ceiling price for Medicaid covered drugs—as a suit to enforce the statute itself. Recognition of a cause of action under the common law thus would contravene congressional intent and create an end-run around this Court's private right of action jurisprudence. Such a cause of action would also seriously disrupt the statutory schemes of both the Medicaid Act and the 340B Act.

I. Statutory Framework

a. *The Medicaid Drug Rebate Program*

Since 1990, the Medicaid Act has "imposed a general requirement that, in order to qualify for Medicaid payments, drug companies must enter into agreements . . . with the Secretary . . . to provide rebates on their Medicaid sales of outpatient prescription drugs." *Pharm. Research & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 652 (2003). Thus, as Spending

Clause legislation, U.S. Const. Art. I, § 8, cl. 1, the Medicaid Act prohibits federal financial participation under Medicaid "with respect to covered outpatient drugs unless there is a rebate agreement in effect under section 1396r-8" through which manufacturers pay rebates to States. 42 U.S.C. § 1396b(i)(10); *accord id*. § 1396r-8(a)(1), (5); J.A. 69-86 (form Medicaid Rebate Agreement).[1]

Approximately 550 manufacturers have entered into rebate agreements with the Secretary covering more than 35,000 drugs. *See* Ctrs. for Medicare & Medicaid Servs. ("CMS"), *Medicaid Drug Rebate Program Overview* (last modified Sept. 27, 2010), http://www.cms.gov/MedicaidDrugRebateProgram/; CMS, *Drug Product Data* (last modified Aug. 3, 2010), http://www.cms.gov/MedicaidDrugRebateProgram/09_DrugProdData.asp. Manufacturers in 2005 paid approximately $11.1 billion in rebates to States. Jean Hearne, Cong. Research Serv., *CRS Report for Congress: Prescription Drug Coverage Under Medicaid* 13 (2008), *available at* http://aging.senate.gov/crs/medicaid16.pdf.

The Medicaid Act sets forth a drug-pricing formula that determines the amount of rebates manufacturers owe to States for covered outpatient drugs. The Act's drug-pricing provisions provided, for the time period relevant to this case, that if the drug is either

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[1] The statutory provisions cited herein and in the Pet. App. are to the statutes in effect during the time period at issue in this case (2001-2008). *See* Pet. App. 74a. Congress recently amended portions of the Medicaid Act and 340B Act. Patient Protection and Affordable Care Act ("PPACA"), Pub. L. No. 111-148, 124 Stat. 119 (2010). Unless expressly noted, these amendments did not materially change the statutory provisions cited herein.

a "single source drug" or an "innovator multiple source drug," the rebate due on each unit paid under a state Medicaid plan is typically either (i) the difference between the AMP and the manufacturer's BP, or (ii) 15.1 percent of the AMP, whichever is greater. 42 U.S.C. § 1396r-8(c)(1)(A), (B), (C) & (c)(2). For other drugs, the rebate is 11 percent of the AMP. *Id*. § 1396r-8(c)(3). In certain circumstances, the Act also requires inflation adjustments that can affect the rebate amount. *Id*. § 1396r-8(c)(2). The Medicaid Act requires manufacturers to report regularly to the Secretary the AMP and BP for each of their covered outpatient drugs. *Id.* § 1396r-8(b)(3)(A).[2]

The Medicaid Act contains several provisions authorizing the Secretary to enforce these drug-pricing requirements. The Act permits the Secretary to "survey wholesalers and manufacturers that directly distribute their covered outpatient drugs, when necessary, to verify manufacturer prices" reported. *Id.* § 1396r-8(b)(3)(B).

The Act also authorizes suspension of the Medicaid Rebate Agreement and a $10,000 penalty per day if a manufacturer fails to report AMP and BP on a timely basis. *Id.* § 1396r-8(b)(3)(C)(i). A manufacturer that knowingly provides false AMP or BP information is potentially subject to civil monetary penalties of up to $100,000 per item. *Id*. § 1396r-8(b)(3)(C)(ii). The Secretary may terminate the Medicaid Rebate

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[2] For the period at issue in this case, AMP equaled the average price paid for the drug by entities in the "retail pharmacy class of trade," and BP equaled the lowest price available to any purchaser within the United States, with certain statutorily-specified exclusions. 42 U.S.C. § 1396r-8(k)(1), (c)(1)(C); *cf*. PPACA § 2503 (amending the definition of AMP and the formula for calculating the Medicaid rebate amount).

Agreement upon a manufacturer's violation of the Agreement or for "other good cause shown." *Id.* § 1396r-8(b)(4)(B)(i).

b. *The Section 340B Drug Ceiling Price Program*

Section 340B of the Public Health Service Act of 1992, 42 U.S.C. § 256b, requires drug manufacturers participating in the Medicaid program to offer discounted drug prices to 340B entities consisting of certain hospitals and clinics, also known as "safety net providers," that receive federal funds. *See id.* § 256b(a)(4) (listing covered entities). In 2009 alone, 340B entities purchased an estimated $6 billion in drugs under the Section 340B program. Krista Pedley & Tom Morris, Health Res. & Servs. Admin., *340B Drug Pricing Program: New Covered Entity Webinar* 5 (2010), *available at* www.hrsa.gov/opa/340bnewlyeligible.ppt. Today, more than 14,500 entities participate in the 340B program. *See* Health Res. & Servs. Admin., *2010 Quarter 3 Statistics for 340B Covered Entities* (2010), *available at* ftp://ftp.hrsa.gov/bphc/pdf/opa/stats_2010_QTR_3.pdf.

The 340B program is also Spending Clause legislation and is inextricably intertwined with the much larger Medicaid drug rebate program. The Medicaid Act dictates that, in order for outpatient prescription drugs to be covered by Medicaid, drug manufacturers must sign an agreement consenting to charge no more than the ceiling price required under the 340B Act. 42 U.S.C. § 1396r-8(a)(1), (5); *see* Joint Explanatory Statement on H.R. 5193, 138 Cong. Rec. S17890 (1992), *reprinted in* 1992 U.S.C.C.A.N. 4186, 4211 (stating that "use of [Medicaid] federal matching funds for payment for a covered outpatient drug [under State Medicaid plans] would be contingent on . . . a manufacturer's entering into . . . an agreement

with the Secretary of Health and Human Services (HHS) under which the manufacturer agrees to provide rebates or discounts to" 340B entities).

The 340B Act incorporates by reference the AMP and BP definitions and pricing methodology from the Medicaid Act and provides that "[t]he Secretary shall enter into an agreement with each manufacturer of covered drugs under which" the manufacturer may not charge more than a statutorily defined price, referred to generally as the "ceiling price." 42. U.S.C. § 256b(a)(1). The ceiling price is "the average manufacturer price for the drug under [the Medicaid Act] in the preceding calendar quarter, reduced by [a] rebate percentage." *Id.*

Thus, the 340B ceiling price equals the AMP defined in the Medicaid Act, *see supra* p. 6 n.2, reduced by the "rebate percentage," which is defined in the 340B Act as the "average total rebate required under" the Medicaid rebate program "with respect to the drug . . . during the preceding calendar quarter; divided by . . . the average manufacturer price for such a unit of the drug during such quarter." 42 U.S.C. § 256b(a)(2)(A). The rebate percentage in turn is based on a statutory formula in the Medicaid Act that requires calculation of, *inter alia*, a manufacturer's BP. *Id*. (citing 42 U.S.C. § 1396r-8(c)). Because of the ceiling price requirements, 340B entities receive large discounts on covered outpatient drugs.

As required by the 340B Act, the statutory ceiling price requirements are set forth in the PPA, which is a form document prepared by the Health Resources and Services Administration ("HRSA") of the Department of Health and Human Services ("HHS"). Pet. App. 165a-181a (form PPA). The PPA recites the

340B Act's obligation that manufacturers charge 340B entities no more than the statutory ceiling price. *Id*. at 170a (PPA ¶ II(a)). The PPA expressly incorporates by reference the manufacturer's statutory drug-pricing obligations to report AMP and BP in accordance with the Medicaid Act's drug rebate provisions. *Id*. at 170a-71a (PPA ¶ II(a)-(d)). The PPA also provides that the Secretary is entitled to "reasonable access to records of the Manufacturer relevant to the Manufacturer's compliance with the terms of the Agreement." *Id.* at 171a (PPA ¶ II(e)).

If the Secretary believes that a manufacturer "has not complied" with Section 340B's requirements, "or has refused to submit reports, or has submitted false information," the PPA authorizes the Secretary to "initiate [an] informal dispute resolution process." *Id*. at 174a (PPA ¶ IV(c)). As part of this process, "the Secretary may require the Manufacturer to reimburse the entity for discounts withheld and can also terminate" the PPA. *Id*. Termination of the PPA means that the manufacturer no longer meets the requirements for Medicaid coverage for the manufacturer's outpatient drugs. *Id.* The PPA further provides that the agreement "shall be construed in accordance with Federal common law." *Id*. at 180a (PPA ¶ VII(g)). The PPA contains no provisions that allow a 340B entity (or any other third party) to enforce its terms.

II. Proceedings Below

a. The County of Santa Clara, California, on behalf of 340B entities in California and California counties that fund 340B entities, brought this putative class action against the petitioners, which are all pharmaceutical manufacturers. The County initially filed suit in state court, alleging that petitioners violated

state law by charging more than the ceiling prices required by the 340B Act. The suit, however, did not identify any particular overcharge by any manufacturer with respect to any drug sold to any covered entity.

Petitioners removed the suit to the U.S. District Court for the Northern District of California, which dismissed the state law claims. The County amended the complaint to add a third-party beneficiary breach of contract claim alleging that county entities "were overcharged for prescription and over-the-counter drugs and pharmaceutical products ('drugs') under the §340B Program pursuant to the [340B] Act." J.A. 30 (2d Am. Compl. ¶ 1). Claiming to be "the intended beneficiaries of the PPA," the County alleged that the class members were "entitled to damages they sustained as a result of [petitioners'] breach of contract." *Id.* at 64 ¶ 104.

The district court again dismissed all the state law claims, noting that "plaintiff's statement of facts is based largely on government reports that never identified the manufacturer, drug or 340B entity." Pet. App. 112a. The court also dismissed the third-party beneficiary breach of contract claim under the PPA, holding that neither the statute nor the PPA reflects an intent to bestow on private parties the right to sue to enforce the 340B Act's pricing requirements. *Id.* at 119a. The County appealed the dismissal of only the third-party beneficiary breach of contract claim under the PPA.

b. The Ninth Circuit reversed and held that federal common law provides a third-party beneficiary breach of contract action for 340B entities to enforce the Act's drug-pricing provisions as incorporated into the PPA. Pet. App. 30a-58a. The court of

appeals held that 340B entities "are intended direct beneficiaries of the PPA and have the right as third parties to bring claims for breach of that contract." *Id*. at 36a.

The court further held "that allowing such suits under the PPA is consistent with Congress' intent in enacting the Section 340B program, *even though the statute itself does not create a federal private cause of action*." *Id.* (emphasis added). The Ninth Circuit found that the claim "presents no far-reaching question that requires expertise or uniformity in administration" of the drug ceiling price program because 340B entities could challenge ceiling prices based only on "the average manufacturer price *reported* to the Secretary" and could not "claim that the reported figure was itself somehow erroneous." *Id*. at 57a (internal quotation marks omitted).

On remand, the district court interpreted the Ninth Circuit's statement that the suit involved only the prices "*reported* to the Secretary" to bar litigation of the drug manufacturers' underlying pricing data and the methods by which they derived the AMP and BP figures reported to the Secretary. *Id.* at 80a-81a.

c. On interlocutory appeal, the Ninth Circuit invited the Secretary to file an amicus brief. *Id.* at 2a n.**. In response to the Ninth Circuit's invitation, the United States, setting forth the considered judgment of the Secretary, expressed the view that it "never imagined that a 340B entity could bring a third-party beneficiary lawsuit" and that such a suit would confer "rights never intended by the PPA's signatories." *See* Brief of the United States of America as Amicus Curiae in Support of the Judgment Below at 13, 21, *County of Santa Clara v. Astra USA, Inc.*, No. 09-15216 (9th Cir. Oct. 27, 2009) ("Gov't

Br."), 2009 WL 4089524. The United States also concluded that discovery in the suit was barred by the Medicaid Act's requirement that the Secretary ensure the confidentiality of drug manufacturers' pricing and drug sales information underlying the calculation of AMPs and BPs. *Id.* at 19-21; *see* 42 U.S.C. § 1396r-8(b)(3)(D).

The United States further explained that the Medicaid drug rebate program confers considerable discretion on drug manufacturers to make reasonable assumptions in calculating AMPs and BPs under the Medicaid Act, which in turn are used to calculate ceiling prices under the 340B Act. Gov't Br. at 4-5. As a result, the United States explained that the recognition of a private right of action to enforce the Medicaid Act's or the 340B Act's pricing requirements would interfere with the Secretary's exclusive responsibility to administer both programs on a nationwide, uniform basis. The United States thus explained that "allowing suits like this would threaten the orderly operation of *both* programs." *Id.* at 19 (emphasis in original).

The United States also reasoned that the manner in which the Medicaid rebates and 340B discounts are calculated create conflicting incentives for recipients of the respective programs. The United States observed that, although relatively high AMPs generally increase the price that manufacturers may charge 340B entities (to the *detriment* of those 340B entities), high AMPs simultaneously increase the manufacturers' much larger rebate obligations to the States (which *benefits* the Medicaid program). *Id.* at 31.

Those conflicting incentives, the United States explained, highlight the need to leave the adminis-

tration and enforcement of the 340B Act and Medicaid Act where Congress placed it, *i.e.*, with the Secretary, who has the expertise to resolve complex issues of pricing methodology and difficult issues of statutory interpretation under both programs. *Id*. at 32.

Soon after the United States filed its amicus brief, the Ninth Circuit issued a superseding decision that reissued the panel's earlier decision but struck the language that had suggested the suit was limited only to the drug-pricing information reported to the government. *Compare* Pet. App. 56a-58a, *with id.* at 28a-29a. Although the court of appeals had invited the Secretary's participation, the superseding decision neither discussed nor deferred to the Secretary's conclusion that permitting the litigation to proceed would be disruptive to both statutory schemes.

SUMMARY OF ARGUMENT

By allowing a private plaintiff to bring a federal common law claim based on a statute that does not provide for any private right of action, the Ninth Circuit's decision contravenes congressional intent and decades of this Court's private right of action jurisprudence. Accordingly, it should be reversed.

A. The 340B Act maximizes health coverage by allowing safety net providers to buy drugs at a discounted price. But Congress chose not to provide an express or implied private cause of action to allow 340B entities to enforce the statute's discount pricing provisions through damages suits.

The law is clear: unless Congress intends to create a cause of action, "a cause of action does not exist and courts may not create one." *Alexander v. Sandoval*, 532 U.S. 275, 286-87 (2001). This black-letter rule

reflects a concern, grounded in separation of powers principles, that the judiciary should not embrace a dispute that Congress has not empowered the courts to resolve. *Stoneridge Inv. Partners, LLC v. Scientific-Atlanta, Inc.*, 552 U.S. 148, 164 (2008). That rule controls this case.

B. The County has conceded at every stage of this litigation—in the district court, in the court of appeals, and in this Court—that the 340B Act confers no private right of action or remedy in favor of 340B entities. C.A. Supp. ER at 66 (9th Cir. Jan. 17, 2007); Pet. App. 22a; Br. in Opp. 4. Nonetheless, the County maintains that this suit seeks not to enforce the 340B Act, but rather to enforce the PPA *contract* between the drug manufacturers and the Secretary. Yet enforcing the contract and enforcing the 340B statute are one and the same.

The County is not a party to the PPA and did not negotiate the contract's terms. Rather, the Secretary promulgated the PPA's language, following the express mandate of Congress. And neither the statute nor the PPA provides third parties with any right to enforce its terms.

In the 340B Act, Congress mandated the drug ceiling price provisions to be incorporated into the terms of the contract. And the PPA correspondingly incorporates by reference the 340B Act's ceiling price provisions. Thus, the County's own complaint makes clear that the 340B Act is the sole source of the precise contractual terms allegedly breached. *See*, *e.g.*, J.A. 41-42, 44 (2d Am. Compl. ¶¶ 32, 39, 40).

C. The Ninth Circuit held that federal common law creates a cause of action for non-parties to enforce the PPA, despite that neither the contract nor the statute, by its terms, allows such lawsuits. If

Congress did not choose to create a private right of action to enforce these statutory terms, then federal common law on its own cannot create such a right.

This Court in *Sandoval* held that an agency cannot by regulation create a cause of action to enforce a statute. 532 U.S. at 291. The agency has no more authority to create private rights to enforce a statute when the agency implements congressional policy via a contract. The PPA thus could not have created a private right of action in favor of 340B entities even if the PPA had attempted to do so explicitly.

A plaintiff may not circumvent congressional intent "by artful pleading" or "the simple expedient of putting a different label" on its cause of action to obtain a remedy not provided by Congress. *Brown v. Gen. Servs. Admin.*, 425 U.S. 820, 833 (1976). When a party seeks to enforce a contractual provision that is *in haec verba* with a statutory provision that Congress mandated to be incorporated into a government contract, that action is indistinguishable from an action to enforce the statute itself.

When this Court has faced analogous attempts by parties to circumvent congressional intent by asserting contract-based claims to enforce other federal statutes, it has held that Congress's intent controls. *See United States v. Erika, Inc.*, 456 U.S. 201, 206-08 (1982); *Univs. Research Ass'n, Inc. v. Coutu*, 450 U.S. 754, 784 (1981). Congressional intent here similarly requires dismissal of the suit.

D. Private enforcement of the 340B Act would seriously interfere with administration of the 340B drug ceiling price program, as well as the vastly larger Medicaid drug rebate program whose pricing methodology is expressly incorporated into the 340B

Act. Oversight over how manufacturers calculate and report BP and AMP—calculations that are exceedingly complex and technical—should not be left to private plaintiffs whose incentives inevitably will diverge from those of the Secretary.

Congress has delegated enforcement of the 340B Act not to 340B entities, but to the Secretary, who has the expertise and perspective to resolve the multitude of difficult issues that determine the calculation of AMP, BP, and the resulting 340B ceiling prices. Congress also provided the Secretary authority to impose substantial penalties and other enforcement mechanisms to ensure that drug manufacturers comply with the 340B Act. Allowing private lawsuits to interfere with the Secretary's judgment would, in the United States's assessment, "conflict with Congress's comprehensive administrative and enforcement scheme" and the agency's ability to administer *both* the 340B Act and the Medicaid Act on a uniform, nationwide basis. Gov't Br. at 13.

E. The federal common law of contracts does not create a cause of action where Congress has failed to do so. A federal court's exercise of federal common law is limited by "the paramount authority of Congress." *Nw. Airlines, Inc. v. Transp. Workers Union of Am.*, 451 U.S. 77, 95 (1981) (internal quotation marks omitted); *City of Milwaukee v. Illinois*, 451 U.S. 304, 313-14 (1981).

Even when federal courts have "express congressional authorization to devise a body of law directly," *Sosa v. Alvarez-Machain*, 542 U.S. 692, 726 (2004), a private party must still demonstrate that Congress intended a private right of action to enforce the statute. Similarly, where Congress has "occupied the field through the establishment of a comprehensive

regulatory program supervised by an expert administrative agency," private remedies are limited to those enacted by Congress. *City of Milwaukee*, 451 U.S. at 317.

All roads in this case lead to the same place: Congress declined to confer a private right of action on 340B entities to enforce the drug price ceiling provisions of the 340B Act. Covered entities therefore cannot invoke the federal common law to sue for damages from an alleged breach of the PPA when the right sought to be enforced is derived from an Act of Congress.

ARGUMENT

This common law breach of contract suit by purported third-party beneficiaries to the PPA should have ended upon the uncontested proposition that Congress did not confer on 340B entities an express or implied private right of action to enforce the 340B Act's drug-pricing obligations. 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. A private right of action to enforce a federal statute must be created by Congress. *E.g.*, *Stoneridge Inv. Partners, LLC v. Scientific-Atlanta*, *Inc.*, 552 U.S. 148, 164 (2008); *Gonzaga Univ. v. Doe*, 536 U.S. 273, 283-84 (2002); *Alexander v. Sandoval*, 532 U.S. 275, 286 (2001); *Cent. Bank of Denver, N.A. v. First Interstate Bank of Denver, N.A.*, 511 U.S. 164, 173 (1994); *Univs. Research Ass'n, Inc. v. Coutu*, 450 U.S. 754, 771-73 (1981); *Touche Ross & Co. v. Redington*, 442 U.S. 560, 568 (1979).

That principle disposes of this case. Congress is the source of the drug-pricing obligations in the contract that the 340B entities seek to enforce. Congress must be the source of a judicial remedy to redress any alleged violation of those obligations. The absence of a private right of action under the statute accordingly forecloses a common law suit by purported third-party beneficiaries to the PPA.

A COMMON LAW THIRD-PARTY BENEFICIARY CLAIM FOR BREACH OF CONTRACT CONFLICTS WITH THE ABSENCE OF A PRIVATE RIGHT OF ACTION UNDER THE STATUTE

A. Only Congress Can Create A Right To Sue To Enforce An Act Of Congress

1. Absent congressional intent to create a private right and remedy, "a cause of action does not exist and courts may not create one, no matter how desirable that might be as a policy matter, or how compatible with the statute." *Sandoval*, 532 U.S. at 286-87. In other words, "[t]he federal judiciary will not engraft a remedy on a statute, no matter how salutary, that Congress did not intend to provide." *Mass. Mut. Life Ins. Co. v. Russell*, 473 U.S. 134, 145 (1985) (quoting *California v. Sierra Club*, 451 U.S. 287, 297 (1981)).

This bedrock principle "reflects a concern, grounded in separation of powers, that Congress rather than the courts controls the availability of remedies for violations of statutes." *Stoneridge*, 552 U.S. at 165 (quoting *Wilder v. Va. Hosp. Ass'n*, 496 U.S. 498, 509 n.9 (1990)). Without congressional intent, the judiciary's recognition of a private right to enforce a statute "necessarily extends its authority to embrace

a dispute Congress has not assigned it to resolve." *Id.* at 164 (internal quotation marks omitted).

"Though the rule once may have been otherwise, *see J. I. Case Co.* v. *Borak*, 377 U.S. 426, 432-433 (1964), it is settled that there is an implied cause of action only if the underlying statute can be interpreted to disclose the intent to create one." *Stoneridge*, 552 U.S. at 164. The Court thus has "retreated" from its "previous willingness to imply a cause of action where Congress has not provided one." *Corr. Servs. Corp. v. Malesko*, 534 U.S. 61, 67 n.3 (2001); *see also id.* at 75 (Scalia, J., concurring) (The *Borak* approach is "a relic of the heady days in which this Court assumed common-law powers to create causes of action—decreeing them to be 'implied' by the mere existence of a statutory or constitutional prohibition."). The once permissive approach to inferring a private right of action has long since been "abandoned." *Sandoval*, 532 U.S. at 287.

Under modern precedent, "recognition of any private right of action for violating a federal statute must ultimately rest on congressional intent to provide a private remedy." *Va. Bankshares, Inc. v. Sandberg*, 501 U.S. 1083, 1102 (1991); *accord Sierra Club*, 451 U.S. at 297 ("[T]he focus of the inquiry is on whether Congress intended to create a remedy." (citing *Univs. Research Ass'n, Inc.*, 450 U.S. at 771-72)). "Like substantive federal law itself, private rights of action to enforce federal law must be created by Congress." *Sandoval*, 532 U.S. at 286. The judicial "task is limited solely to determining whether Congress intended to create the private right of action asserted." *Touche Ross & Co.*, 442 U.S. at 568. The statute must reveal "an intent to create not just

a private right but also a private remedy." *Sandoval*, 532 U.S. at 286.

2. Judicial power to infer a private right of action is especially limited where, as here, a private party seeks to enforce provisions of Spending Clause legislation. *See, e.g.*, *Gonzaga Univ.*, 536 U.S. at 283; *Sandoval*, 532 U.S. at 286; *Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1 (1981). "[I]f Congress intends to impose a condition on the grant of federal moneys, it must do so *unambiguously*." *Pennhurst*, 451 U.S. at 17 (emphasis added); *see, e.g.*, *Barnes v. Gorman*, 536 U.S. 181, 186 (2002); *Davis v. Monroe Cnty. Bd. of Educ.*, 526 U.S. 629, 640 (1999). In the few cases where the Court has found Spending Clause legislation to give rise to enforceable rights, such as in Title VI of the Civil Rights Act of 1964 and Title IX of the Education Amendments of 1972, "Congress spoke in terms that could not be clearer." *Gonzaga Univ.*, 536 U.S. at 280 (internal quotation marks omitted).

The Section 340B ceiling price and Medicaid drug rebate programs are Spending Clause enactments. *See supra* pp. 4-5, 7-8. The "typical" remedy for noncompliance with Spending Clause legislation is for the federal government to terminate provision of funds. *Gonzaga Univ.*, 536 U.S. at 280 (quoting *Pennhurst*, 451 U.S. at 28). The PPA follows precisely this approach—it authorizes the Secretary to terminate the agreement if a manufacturer fails to comply with its obligations, thus barring the manufacturer from receiving coverage for its outpatient drugs under Medicaid. *See* Pet. App. 174a (PPA ¶ IV(c)).

Thus, any right of action by claimed beneficiaries of those programs must be based on "clear and unambi-

guous" congressional intent to create both a private right and a private remedy. *Gonzaga Univ.*, 536 U.S. at 284, 290. As demonstrated below, the requisite clarity necessary to find a private cause of action in this case is manifestly absent.

B. This Suit Seeks Private Enforcement Of A Statute

1. The County has dressed up an implied right of action claim in breach-of-contract clothes. The litigation began when the County filed this putative class action alleging that 340B entities "were overcharged for prescription and over-the-counter drugs and pharmaceutical products ('drugs') under the §340B Program *pursuant to the [340B] Act*." J.A. 30 (2d Am. Compl. ¶ 1) (emphasis added).[3] The complaint alleged, based on information and belief, *id*. at 32 ¶ 7, that those entities were charged more than the "*statutorily defined* discount on outpatient drugs." *Id.* at 30 ¶ 2 (emphasis added).

This suit thus unquestionably seeks to enforce the pricing obligations of the 340B Act. Indeed, the complaint repeatedly acknowledges that the 340B Act is the source of the contractual term allegedly breached. *See e.g.*, *id.* at 41-42 ¶ 32 ("§340B requires pharmaceutical manufacturers to ensure that §340B Participants pay no more than the 'ceiling price,' a discounted price compared to the average manufacturers' price for any pharmaceutical product."); *id.*

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[3] Respondent filed a third amended complaint while its request for interlocutory review was pending. The third amended complaint added new plaintiffs and retained the third-party beneficiary breach of contract claim based on the statutory ceiling price obligations that are incorporated into the PPA. Third Am. Compl. ¶¶ 72-79 (filed Dec. 23, 2008).

at 44 ¶ 39 ("Section 340B . . . requires [drug manufacturers] to agree to be bound by the PPA in order to participate in the §340B Program."); *id.* ¶ 40 ("Under both §340B and the PPA, [drug manufacturers] are required to ensure that the §340B Participants . . . pay no more for any product that the §340B ceiling price.").

2. Notwithstanding that the gravamen of this suit is that petitioners allegedly violated the ceiling price requirements of the 340B Act, the County did not bring its claim directly under the 340B statute. To the contrary, in the trial court, the County acknowledged that "there is no federal private right of action under the 340B Program." C.A. Supp. ER 66; *see also* Pet. App. 22a (noting "Santa Clara's concession before the district court that there is no private federal cause of action under § 256b.").

In the Ninth Circuit, the County likewise observed that "the statute here neither creates nor precludes any remedy, it simply provides for a contract." Appellants' Reply Brief at 10, *County of Santa Clara v. Astra USA, Inc.*, No. 06-16471 (9th Cir. Feb. 20, 2007), 2007 WL 894881; *accord* Pet. App. 22a n.15. And in this Court, the County represented that "the County's position is not that the statute creates an implied right of action to sue for violation of the statute." Br. in Opp. 4 (internal brackets and quotation marks omitted); *id*. ("[T]he County seeks to vindicate the rights of its covered entities under contracts . . . that were created by a federal statute which expressly provides them no remedy . . . .").

Instead of formally bringing a claim under the 340B Act, the County asserted a "federal common law" third-party beneficiary claim for breach of contract. Appellants' Opening Brief at 3, *County of*

Santa Clara v. Astra USA, Inc., No. 06-16471 (9th Cir. Nov. 22, 2006), 2006 WL 4040345; J.A. 63-64 (2d Am. Compl. ¶¶ 101-04). That claim alleges that 340B entities are third-party beneficiaries to the PPA on the theory that the contracting parties intended that 340B entities "pay no more than the 340B ceiling price for covered drugs." J.A. 64 (2d Am. Compl. ¶ 102). Quoting paragraphs II and II(a) of the PPA, the complaint alleges that the PPA confers a right of judicial enforcement on behalf of covered entities: "Pursuant to requirements under section 340B . . . the Manufacturer agrees . . . to charge covered entities a price for each unit of the drug that does not exceed an amount equal to the AMP for the covered outpatient drug reported . . . ." *Id*.

The contract claim further contends that the manufacturers "breached, and continue to breach, their contractual obligations under the PPA by charging plaintiffs and the Class members more than the §340B ceiling price for covered drugs." *Id.* ¶ 103. The County thus seeks to prove that 340B entities were charged more than the 340B Act ceiling price by showing that manufacturers miscalculated and misreported to the Secretary the AMP and BP components of the 340B ceiling price. As the County described its claim, "[s]ince the ceiling price is dependent on the AMP and best price, logically and legally, plaintiffs would need to discover the data that comprised the prices charged." Pl.'s Pet. to Appeal at 5, *County of Santa Clara v. Astra USA, Inc.*, No. 08-80200 (9th Cir. Dec. 11, 2008); *cf.* 42 U.S.C. §§ 256b(a)(2)(A), 1396r-8(c)(1)(A) & (C) (setting forth BP as part of the formula for determining the 340B "rebate percentage").

The substantive right that the County seeks to enforce thus derives from an Act of Congress. The allegedly breached contractual term—the requirement not to charge 340B entities more than the 340B ceiling price—is *statutorily required*. The Medicaid Act, as a condition of statutory coverage for outpatient drugs, mandates that drug manufacturers enter into a PPA under which they agree not to charge 340B entities more than the Section 340B ceiling price. 42 U.S.C. § 1396r-8(a)(1), (5).

The 340B Act in turn explicitly requires the PPA to provide that the amount the manufacturer charges a covered entity for covered drugs cannot "*exceed an amount equal to the average manufacturer price for the drug under [the Medicaid Act] . . . reduced by the rebate percentage*." 42 U.S.C. § 256b(a)(1) (emphasis added); *compare* Pet. App. 170a (PPA ¶II(a)). The PPA also incorporates the statutory requirement that manufacturers determine the 340B ceiling price using the AMP and BP figures calculated under the Medicaid Act. Section II(a) provides that the manufacturers must use the AMP "reported . . . to the Secretary in accordance with the Manufacturer's responsibilities under [the Medicaid Act]." Pet. App. 170a (PPA ¶II(a)).

The PPA includes definitions of AMP and BP, which "have the meanings specified in the [340B] Act and [the Medicaid Act]." *Id.* at 165a (PPA ¶ I). Thus, at every point in the determination of the ceiling price, manufacturers are directed by the PPA to comply with the provisions of the 340B Act and the relevant drug rebate provisions of the Medicaid Act. As the Ninth Circuit below candidly acknowledged, the PPA is not the product of "a conventionally negotiated contract." *Id.* at 20a n.13. In the words of the

court of appeals: "Santa Clara seeks enforcement of an obligation created by a nationwide federal contract whose terms are *mandated by federal statute*." *Id*. at 9a n.5 (emphasis added).

C. A Third-Party Beneficiary Suit For Breach Of Contract Would Circumvent The Absence Of A Private Right Of Action Under The 340B Act

1. When a third party seeks to enforce a contractual provision that is *in haec verba* with a statutory provision that Congress mandated be incorporated into a contract, recognition of a common law third-party beneficiary breach of contract action conflicts with the bedrock requirement that only Congress may authorize private enforcement of an Act of Congress. This case well illustrates the point. Although the Ninth Circuit expressly assumed that Congress did *not* intend the 340B Act's pricing obligations to be enforced by private parties, Pet. App. 8a, 22a n.15, 29a, the court of appeals invented such a right anyway under the federal common law of contract.

The Ninth Circuit's holding erroneously assumes the Secretary by contract may confer a private right of action by 340B entities that is not provided in the statute itself. This Court's decision in *Alexander v. Sandoval*, 532 U.S. 275 (2001), establishes that even an affirmative intent by the Executive Branch to create substantive rights in the PPA could not trump the absence of an implied right of action in the statute. The Court in *Sandoval* squarely rejected the principle that "language in a [government] regulation can conjure up a private cause of action that has not been authorized by Congress." 532 U.S. at 291. The Court explained that "[a]gencies may play the

sorcerer's apprentice but not the sorcerer himself." *Id*.

Sandoval forecloses any argument that the parties, by executing the PPA, could have somehow conferred a private right of action on 340B entities despite the lack of congressional intent to do so. The Secretary had no more authority to create a private cause of action to enforce the 340B Act when she entered into the PPA than had she by regulation purported to create a private right of action in favor of Section 340B entities. The PPA thus could not override the absence of an implied right of action even if the PPA explicitly had purported to create a private right of action in favor of 340B entities.

2. In analogous contexts, this Court has held that congressional intent is controlling over the contracting parties' intent. In *Universities Research Association, Inc. v. Coutu*, 450 U.S. 754 (1981), this Court looked to congressional intent, rather than the terms of a contract, to determine that a private party had no right to sue to enforce statutory rights incorporated in the contract. That decision held that a purported beneficiary of a government contract could not sue for private enforcement of minimum-wage requirements set forth in the Davis-Bacon Act, 40 U.S.C. § 276a(a), which the plaintiff-employee alleged were incorporated into the contract. 450 U.S. at 784. The plaintiff did not pursue a private right of action under the Davis-Bacon Act but asserted that the contractor breached the contract that had, by operation of law, incorporated the statutory wage obligations. *Id.* at 764-67; *Coutu v. Univs. Research Ass'n, Inc.*, 595 F.2d 396, 397-98 (7th Cir. 1979) (describing claims).

In holding that the plaintiff had no right to sue, the Court exclusively focused on whether Congress intended to create a private right of action. 450 U.S. at 770-71. This Court found the fact "that an enactment is designed to benefit a particular class does not end the inquiry; instead, it must also be asked whether the language of the statute indicates that Congress intended that it be enforced through private litigation." *Id.* at 771. *Universities Research Association* thus confirms that when a private party seeks to enforce statutory rights—either under the statute itself or under a government contract incorporating the statutory requirement—the dispositive question is whether Congress intended that the statutory obligation "be enforced through private litigation." *Id*.

This Court similarly has held that private parties may not circumvent congressional intent to withhold a private right of action by dressing up a claim to enforce statutory requirements in breach-of-contract garb. In *United States v. Erika, Inc.*, 456 U.S. 201, 206-08 (1982), the Court held that the structure of the Medicare Act reflected an implied legislative intent to preclude judicial review of determinations by private insurance carriers of the amount of benefits payable under Part B of the Medicare program, 42 U.S.C. § 1395j *et seq.* (1976). The Court rejected the plaintiff's claim that, separate from any rights arising under the Act, a Medicare provider derived a substantive right to seek review of the carrier's determination "from an implied-in-fact contract with the United States, or *as a third-party beneficiary to [the carrier's] contract with the United States*." 456 U.S. at 211 n.14. (emphasis added).

Those "arguments fail because any such contracts with the United States necessarily would include the statutory preclusion of review of hearing officers' determinations regarding the amount of Part B benefits." *Id*. The Court reasoned that the judicial task was "at an end" because Congress did not intend to provide for judicial review of the carrier's determination. *Id.* at 211. The same principle precludes 340B entities from using a pleading device to evade the absence of an implied right of action to enforce the 340B Act.

A plaintiff may not circumvent congressional intent "by artful pleading" or "the simple expedient of putting a different label" on his cause of action to obtain a remedy not provided by Congress. *Brown v. Gen. Servs. Admin*., 425 U.S. 820, 833 (1976); *see also Tenet v. Doe*, 544 U.S. 1, 8 (2005) (holding that preclusion of judicial review under *Totten v. United States*, 92 U.S. 105 (1876), applies "[n]o matter the clothing in which [plaintiffs] dress their claims"). Because the 340B Act does not confer on 340B entities a right of action, the PPA between the government and the manufacturers "necessarily . . . include[s] the statutory preclusion of review" of the drug manufacturers' drug-pricing determinations. *Erika, Inc.*, 456 U.S. at 211 n.14.

3. A third-party beneficiary claim for breach of contract renders the absence of a private right of action meaningless since the substantive right to enforce the drug-pricing requirements is the same under either doctrine. A private right of action by third parties to enforce the *contract's* ceiling price obligations is indistinguishable from a private right of action to enforce the *statutory* ceiling price obligations set forth in the contract.

When Congress requires a statutory obligation to be incorporated into a government contract, a private suit under a third-party beneficiary theory "is but another aspect of the implied right of action argument." *Hodges v. Atchison, Topeka & Santa Fe Ry. Co.*, 728 F.2d 414, 416 (10th Cir. 1984). Common law third-party beneficiary suits "are indirect attempts at privately enforcing the [statutory requirements] contained in the [Act]," and would interfere with congressional intent "to the same extent as would a cause of action directly under the statute." *Grochowski v. Phoenix Constr.*, 318 F.3d 80, 86 (2d Cir. 2003) (internal quotation marks omitted). Where "no private right of action exists under the relevant statute," a plaintiff's efforts to bring common law claims "are clearly an impermissible 'end run' around the [Act]." *Id.*; *cf. Pharm. Research & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 683 (Thomas, J., concurring) (questioning whether a third-party beneficiary breach of contract claim would conflict with the Court's implied right of action and Spending Clause cases).

The Ninth Circuit's decision vividly illustrates the extent to which the creation of a third-party beneficiary right in these circumstances would circumvent the stringent requirements necessary for inferring a private right of action. The third-party beneficiary doctrine gives parties to a contract "the power, if they so intend, to create a right in a third person." Restatement (Second) of Contracts § 304 cmt. b (1981). The court of appeals thus held that "the parties to the PPA clearly intended to grant covered entities enforceable rights as intended beneficiaries of that agreement." Pet. App. 13a. But because Congress created the ceiling price obligations, only

Congress can create a private right to enforce those obligations.

As discussed, no amount of intent on the part of the parties, including the Executive Branch, to create a private right or remedy can trump the fact that Congress did not provide for such a remedy in the statute. *See supra* pp. 25-26. And here, the parties' intent and Congress's intent are one and the same. Indeed, the Ninth Circuit seemingly ignored the view of the United States that the Secretary "never imagined that a 340B entity could bring a third-party beneficiary lawsuit." Gov't Br. at 21. As the United States aptly stated, letting this suit proceed would "accord . . . rights never intended by the PPA's signatories." *Id.* at 13.

The court of appeals nonetheless reasoned that it was "unable to discern any substantial purpose of the PPA *other* than to grant eligible covered entities a discount on covered drugs." Pet. App. 15a. The court accordingly held that because the 340B program directly benefits covered entities in the form of drug discounts, 340B entities are intended third-party beneficiaries of the contract. As stated by the court of appeals: "the right to sue inheres in one's status as an intended beneficiary." *Id.* at 11a.

That analysis is categorically barred by this Court's settled private right of action and Spending Clause jurisprudence, which hold that a private remedy cannot be based on the status of the plaintiff as an intended beneficiary of a federal program. The relevant inquiry is whether "Congress intended to create a federal right." *Gonzaga Univ.*, 536 U.S. at 283 (emphases removed). "The question is not simply who would benefit from the Act, but whether Congress intended to confer federal rights upon those

beneficiaries." *Sierra Club*, 451 U.S. at 294; *accord, e.g., Sandoval*, 532 U.S. at 286-87; *Univs. Research Ass'n*, 450 U.S. at 771; *Transamerica Mortg. Advisors, Inc. v. Lewis*, 444 U.S. 11, 24 (1979). "[T]he question whether Congress intended to create a private right of action is definitively answered in the negative where a statute by its terms grants no private rights to any identifiable class." *Gonzaga Univ.*, 536 U.S. at 283-84 (brackets and quotation marks omitted).

That analysis should have been the beginning and end of this case. The County for good reason conceded that Congress did not confer on 340B entities enforceable rights and private remedies. The 340B Act provides that "[t]he Secretary shall enter into an agreement with each manufacturer of covered drugs under which the amount required to be paid . . . to the manufacturer for covered drugs . . . purchased by a covered entity . . . does not exceed [the ceiling price]." 42 U.S.C. § 256b(a)(1).

Statutory language "simply 'phrased as a directive to federal agencies engaged in the disbursement of public funds,'" "provides no support for the implication of a private remedy." *Univs. Research Ass'n*, 450 U.S. at 772-73 (quoting *Cannon v. Univ. of Chi.*, 441 U.S. 677, 693 n.14 (1979)); *see also Gonzaga Univ.*, 536 U.S. at 287; *Sandoval*, 532 U.S. at 288. And no provision of the 340B Act contains the clear and unambiguous language necessary to infer congressional intent to create a private right of action. *Sandoval*, 532 U.S. at 288.

The Ninth Circuit concluded that the third-party beneficiary claim was permissible because the 340B Act "does not abrogate" private contract suits by third parties. Pet. App. 24a n.16. The court of appeals

based this conclusion on the rule that the third-party beneficiary doctrine does not apply to the extent that application "would contravene the policy of the law authorizing the contract or prescribing remedies for its breach." Pet. App. 27a (quoting Restatement (Second) of Contracts § 313(1)). But that rule starts from the wrong premise—that third parties can derive rights from contracting parties unless a court ascertains a congressional intent to foreclose the right.

There is no free-standing cause of action under the federal common law in favor of 340B entities that Congress must affirmatively "abrogate." Rather, Congress must affirmatively authorize the cause of action. *See supra* pp. 18-21; *see also Mertens v. Hewitt Assocs.*, 508 U.S. 248, 255 n.5. (1993) ("The dissent expresses its certitude that 'the statute clearly does not bar such a suit.' That, of course, is not the issue. The issue is whether the statute affirmatively *authorizes* such a suit." (citation omitted) (emphasis in original)). Congress did not do so here. The court of appeals accordingly erred in arrogating to itself the power to create an action on behalf of 340B entities absent congressional authorization.

D. Private Suits Would Seriously Disrupt The Comprehensive Statutory Schemes Under The 340B Act And The Medicaid Act

1. As the Secretary explained, allowing a private right of action would also interfere with the Secretary's orderly regulation of both the 340B program and the much larger Medicaid program. *See* Gov't Br. at 19. Disregarding that view, however, the Ninth Circuit sought to buttress its recognition of a private right of action by opining that private

suits are "wholly compatible with the Section 340B program's objectives" to ensure "that drug companies comply with their obligations under the program and provide those discounts." Pet. App. 26a, 27a. The court similarly stated its view that it "'seemed more sensible' to permit third parties to sue as intended beneficiaries than to 'place the entire burden of enforcement' on the government." *Id.* at 27a (quoting *Price v. Pierce*, 823 F.2d 1114, 1121 (7th Cir. 1987)).

By shifting its attention away from the statute as enacted by Congress, the court of appeals also ignored the considered judgment of the Secretary that permitting a private suit to enforce the drug ceiling price provision "would conflict with Congress's comprehensive administrative and enforcement scheme" and the Secretary's ability to administer *both* the 340B Act and the Medicaid Act on a uniform, nationwide basis. Gov't Br. at 13, 19.

As discussed, Congress implemented the 340B program using pricing metrics—AMP and BP—that it adopted unchanged from the considerably larger Medicaid rebate program. 42 U.S.C. § 256b(a) (incorporating by reference 42 U.S.C. § 1396r-8). The United States therefore explained that because "disputes over AMP and Best Price are challenges to prices reported as part of the Medicaid Rebate Program[,] plaintiff's lawsuit squarely implicates CMS's oversight of *that* program." Gov't Br. at 14 (emphasis in original). Therefore, "because AMP and Best Price affect the Medicaid Rebate Program *and* the 340B Program, allowing suits like this would threaten the orderly operation of *both* programs." *Id.* at 19 (emphasis in original).

The court of appeals departed from congressional intent in assuming that private litigants and judges

and juries were well-suited to navigate and resolve the multitude of exceedingly complex and technical issues that determine the calculation of AMP, BP, and the resulting 340B ceiling prices. *See* Gov't Br. at 4-5; 72 Fed. Reg. 39,142, 39,164 (July 17, 2007). For AMP alone, manufacturers must decide which sales, discounts, and other business arrangements to include in or exclude from the AMP pricing methodology for over 35,000 covered outpatient drugs. *See* 42 U.S.C. § 1396r-8(k)(1); Gov't Br. at 4-5.

Manufacturers devote extensive resources and expertise to getting these calculations right. "A large pharmaceutical company . . . typically has a large team of analysts, IT staff and managers devoted full-time to performing these calculations." Brown Decl. in Support of Defs.' Joint Mot. for Protective Order ¶ 5, *County of Santa Clara v. Astra USA, Inc.*, No. 05-cv-03740 (N.D. Cal. Feb. 4, 2010) ("Brown Decl."). The work involves multiple departments and trained expert employees. *See* Black Decl. in Support of Joint Mot. for Partial Judgment on the Pleadings ¶¶ 6-7, *County of Santa Clara v. Astra USA, Inc.*, No. 05-cv-03740 (N.D. Cal. Feb. 4, 2010) ("Black Decl.").

The difficulty of calculating AMP and BP has been compounded by a "lack of clear CMS guidance." Gov't Accountability Office, GAO-05-102, *Medicaid Drug Rebate Program: Inadequate Oversight Raises Concerns About Rebates Paid to States* 15 (2005). Throughout the 17 years preceding the Secretary's issuance of regulations, *see* 72 Fed. Reg. 39,142, manufacturers were guided by 79 informal "releases" that created, rather than resolved, interpretive and calculation issues. Gov't Br. at 5. For example, there was considerable confusion in the industry regarding whether administrative fees and rebates to Pharmacy

Benefit Managers (PBMs) should be included in AMP and BP. *See* Gov't Accountability Office, *supra*, at 12-15, 19-22 (explaining that "the rebate program does not clearly address certain concessions that are negotiated by PBMs on behalf of third-party payers").

In response, CMS issued Rebate Release 28:

> Best price is based on the lowest price available to any entity except those excluded under the statute or rebate agreement. Therefore, where the use of the PBM by manufacturers establishes lower prices, these lower prices should be reflected in best price calculations. . . . Drug prices to PBMs have no effect on the AMP calculations unless the PBM is acting as a wholesaler as defined in the rebate agreement.

CMS, Medicaid Drug Rebate Program Release No. 28 (1997), *available at* http://www.cms.gov/MedicaidDrugRebateProgram/03_DrugMfrReleases.asp. The Government Accountability Office ("GAO"), however, was unsure from that release how PBM-negotiated manufacturer payments should be reflected in AMP and BP. *See* Gov't Accountability Office, *supra*, at 21-22. Rebate Release 29 then exacerbated the confusion by changing the last sentence to "[w]e *generally* consider drug prices to PBMs as having no effect on the AMP calculations unless the PBM is acting as a wholesaler as defined in the rebate agreement." CMS, Medicaid Drug Rebate Program Release No. 29 (1997) (emphasis added), *available at* http://www.cms.gov/MedicaidDrugRebateProgram/03_DrugMfrReleases.asp.

CMS subsequently issued Rebate Release 30, announcing that "[w]e have been informed that there may have been some confusion concerning the intent

of the information published in Manufacturer Release Numbers 28 and 29 . . . . We are currently re-examining the issue and hope to clarify our position in the near future." CMS, Medicaid Drug Rebate Program Release No. 30 (1997), *available at* http://www.cms.gov/MedicaidDrugRebateProgram/03_DrugMfrReleases.asp. Rebate Release 30 was issued in 1997, but CMS did not issue the promised clarification until the 2007 regulations, which acknowledged "the lack of a clear definition of AMP or specific guidance regarding which retail prices should be included in AMP." 72 Fed. Reg. at 39,146.

Moreover, Congress recently altered the statutory definition of AMP. *See* Patient Protection and Affordable Care Act ("PPACA"), Pub. L. No. 111-148, § 2503, 124 Stat. 119 (2010). The Secretary accordingly withdrew the regulations governing the calculation of AMP, and advised manufacturers simply to "rely on the statutory language." Medicaid Program; Withdrawal of Determination of Average Manufacturer Price, Multiple Source Drug Definition, and Upper Limits for Multiple Source Drugs 13 (to be published Nov. 15, 2010), *available at* http://www.ofr.gov/OFRUpload/OFRData/2010-28649_PI.pdf. Until the Secretary issues further guidance, manufacturers inevitably will face considerable uncertainty with respect to the statutory drug-pricing methodology. Private suits thus could unjustifiably penalize manufacturers for the lack of agency guidance if courts (and perhaps juries) impose liability because they disagree with a manufacturer's judgments about pricing methodology.

Judicial second-guessing would also conflict with the regulatory regime to the extent it permits manufacturers to employ varying calculation methods for

AMP and BP, so long as their methodology is reasonable. Gov't Br. at 5. "[I]n the absence of specific statutory or agency guidance," the Secretary has "allowed manufacturers to make reasonable assumptions in their calculations of AMP and Best Price, consistent with the intent of 42 U.S. § 1396r-8, federal regulations, and the terms of the agreement." *Id.* (internal brackets and quotation marks omitted); *accord* J.A. 78-79 (Medicaid Rebate Agreement § II(i)); 72 Fed. Reg. at 39,171. It is wholly implausible that Congress contemplated that any of the thousands of 340B entities could require courts to sort through and perhaps second-guess the drug manufacturers' decisions with respect to millions upon millions of drug transactions to determine whether those decisions were reasonable.

2. Private suits would also conflict with Congress's decision to provide for enforcement by the Secretary. The United States correctly concluded that private suits would "undermine HHS's role" in administering and enforcing both the 340B and Medicaid programs. Gov't Br. at 13. Such suits also would "permit enforcement without the check imposed by prosecutorial discretion." *Sosa v. Alvarez-Machain*, 542 U.S. 692, 727 (2004).

And, as mentioned, the PPA permits the Secretary to initiate an informal dispute resolution process on behalf of a covered entity and, if warranted, the Secretary can require a manufacturer to reimburse a covered entity for discounts withheld. Pet. App. 174a (PPA ¶ IV(c)); *see also* 61 Fed. Reg. 65,406 (Dec. 12, 1996) (implementing a voluntary dispute resolution program). The Ninth Circuit found that only the PPA, and not the 340B Act, authorized the Secretary to enforce the 340B ceiling price. Pet. App. 26. The

court's analysis, however, ignored the interrelationship between the 340B program and the Medicaid rebate program under which drug manufacturers report to the Secretary the AMP and BP figures that are the basis for the 340B drug discounts. *See supra* p. 8.[4]

The Medicaid Act authorizes serious penalties for a manufacturer's violation of the rules governing calculation and reporting of AMP and BP. The Medicaid statute allows the Secretary to impose fines of up to $10,000 per day for failure to report AMP and BP information, and penalties of up to $100,000 per instance of knowingly providing false AMP and BP information. 42 U.S.C § 1396r-8(b)(3)(C); *see also* PPACA § 7102(a) (adding 42 U.S.C. § 256b(d)(1)(B)(vi) to impose civil monetary penalties of up to $5,000 per instance of a manufacturer knowingly and intentionally charging a covered entity a price that exceeds the 340B ceiling price). The Secretary also may terminate the Medicaid Rebate Agreement for violation of the AMP and BP reporting requirements. 42 U.S.C. § 1396r-8(b)(4)(B)(i). The Medicaid Rebate Agreement further permits the Secretary to audit a manufacturer's AMP and BP figures that underlie the 340B ceiling price and Medicaid rebate amount and, if necessary, require manufacturers to recal-

[4] PPACA amends the 340B Act to require the Secretary to promulgate regulations to establish an administrative process to resolve covered entities' claims that manufacturers violated the PPA or the 340B Act. PPACA § 7102(a) (adding 42 U.S.C. § 256b(d)(3)). The resolution under that process "shall be a final agency decision and shall be binding upon the parties involved, unless invalidated by an order of a court of competent jurisdiction." *Id.* (adding 42 U.S.C. § 256b(d)(3)(C)). The Secretary has solicited input from interested parties but has not yet proposed regulations. 75 Fed. Reg. 57,233 (Sept. 20, 2010).

culate them. J.A. 79 (Medicaid Rebate Agreement § III(c)).

3. Private rights of action also would impose unwarranted and costly administrative burdens on drug manufacturers that already devote significant resources to comply with both the 340B and Medicaid drug rebate programs. For example, the suit here does not allege *any* specific overcharge for any particular drug by any particular drug manufacturer. The complaint therefore does not identify any individual 340B entity that paid a higher price for covered drugs than required under the 340B drug ceiling price program. As the district court observed, this suit "is based largely on government reports that never identified the manufacturer, drug or 340B entity." Pet. App. 112a; *see also* Gov't. Br. at 10 ("Plaintiff did not explain why it thought it had been overcharged for any specific drug."); Pet. App. 29a ("[T]he nature of the breaches Santa Clara will seek to prove is unclear . . . .").

This suit nonetheless has forced petitioners to collect and produce confidential and sensitive drug-pricing and sales information on a national basis for millions of drug sales transactions. Pet. App. 74a-77a. The extent and quantity of the information sought by the County is breathtaking. For petitioner GlaxoSmithKline, for instance, the County sought "more than 100 million [computer] data records per quarter" that the company sorts and analyzes for its AMP and BP calculations. Brown Decl. ¶ 9. That size and scope is typical for other manufacturers as well. *See, e.g.*, Le Compte Decl. in Support of Joint Mot. for Partial Judgment on the Pleadings ¶ 5, *County of Santa Clara v. Astra USA, Inc.*, No. 05-cv-03740 (N.D. Cal. Feb. 4, 2010) ("approximately 150

million sales records" for Pfizer); Black Decl. ¶ 8 ("over 30 million sales transactions" for Wyeth).

These burdensome discovery requests violate the confidentiality provision of the Medicaid Act. The confidentiality provision provides that, "[n]otwithstanding any other provision of law, information disclosed by manufacturers . . . under [42 U.S.C. § 1396r-8(b)] . . . is confidential and shall not be disclosed by the Secretary . . . in a form which discloses the identity of a specific manufacturer . . . [or] prices charged for drugs by such manufacturer. . . ." 42 U.S.C. § 1396r-8(b)(3)(D).

The Secretary "interprets this confidentiality provision to bar her from entering into any contractual agreement that allows 340B entities to obtain discovery about AMP and Best Price calculations," and concludes that, because the confidentiality provision applies "notwithstanding any other provision of law," "it is irrelevant . . . that discovery would be compelled by court rules." Gov't. Br at 20-21. The Secretary's interpretation of the confidentiality provision is reasonable and entitled to deference. *Id.* (citing *Beck v. PACE Int'l Union*, 551 U.S. 96, 104 (2007)). Allowing private suits, and their corresponding discovery, would thus conflict with the Medicaid Act's requirement that the Secretary ensure the confidentiality of drug manufacturers' pricing and drug sales information.

Private enforcement of the 340B program also would threaten to impose conflicting obligations on drug manufacturers under both the Medicaid drug rebate and 340B ceiling price programs. Due to differences in the pricing formulas under the two statutes, changes in AMP can have opposite effects on Medicaid rebate calculations and 340B ceiling price

calculations. For example, a reduction in AMP may cause a manufacturer's Medicaid rebate payments to the States to decline (*e.g.*, because 15.1 percent of a lower AMP results in a lower rebate amount) while increasing the discount that 340B entities may receive (*e.g.*, because the AMP minus the unit rebate amount results in a lower number).

Such a decrease in Medicaid rebates would be a detriment to the States under the larger Medicaid program, yet the decrease in the 340B ceiling price simultaneously would be an advantage to a 340B entity. Thus, States, under the Medicaid program, have the opposite incentive—to maintain the higher reported AMPs, which would increase the rebates the States receive. As the United States informed the court of appeals, "if both 340B entities and states can bring separate suits over AMP calculations, there is a real possibility that manufacturers could be subject to inconsistent obligations." *Id*. at 31-32. "[B]ecause AMP and Best Price affect the Medicaid Rebate Program *and* the 340B Program, allowing suits like this would threaten the orderly operation of *both* programs" and undermine the agency's role "to resolve issues for both programs at once." *Id.* at 19, 32 (emphasis in original).

The County's argument, Br. in Opp. 34, that private suits produce a "win-win" because a lower BP generally benefits States as well as 340B entities, ignores and does not refute the government's view that States and 340B entities have conflicting incentives with respect to AMP. Gov't Br. at 31. 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.

E. The Federal Common Law Of Contracts Is Not A Basis To Create A Private Right To Enforce The 340B Act

1. The PPA is a federal contract to which the United States is a party, and the PPA accordingly provides that it "shall be construed in accordance with Federal common law." Pet. App. 180a (PPA ¶ VII(g)). That choice-of-law provision thus identifies federal common law, as opposed to that of any specific State, as the source of law for interpreting the document. It is well settled that federal common law principles govern the contractual obligations of the United States. *E.g.*, *Clearfield Trust Co. v. United States*, 318 U.S. 363, 366 (1943); *Mobil Oil Expl. & Producing Se., Inc. v. United States*, 530 U.S. 604, 607 (2000).[5]

But that provision is not a license for the federal courts to create substantive rights for an entire new class of parties to whom Congress declined to grant those rights. A court's exercise of federal common law is limited by "the paramount authority of

[5] The Ninth Circuit in a footnote stated that the court was not resolving "whether federal or state law creates the cause of action underlying [the County's] contract claim." Pet. App. 8a n.5. The court similarly noted that the 340B Act "does not preempt a state law contract cause of action, if that indeed is how [the County's] claim should be characterized." *Id*. at 24a n.16. Those statements are seriously mistaken in light of (1) the PPA's designation of federal common law as the choice of law, *id*. at 180a (PPA ¶ VII(g)), (2) the United States's status as a party to the contract, *Clearfield Trust Co.*, 318 U.S. at 366, and (3) the court of appeals's repeated invocation of "*federal* common law" to recognize a right of action by Section 340B covered entities, *see, e.g.*, Pet. App. 10a, 22a, 26a, 27a (emphasis added).

Congress." *Nw. Airlines, Inc. v. Transp. Workers Union of Am.*, 451 U.S. 77, 95 (1981) (internal quotation marks omitted); *City of Milwaukee v. Illinois*, 451 U.S. 304, 313-14 (1981). "[T]he usual and important concerns of an appropriate division of functions between the Congress and the federal judiciary," apply equally when federal common law is implicated. *City of Milwaukee*, 451 U.S. at 313.

"There is no federal general common law." *Erie R.R. Co. v. Tompkins*, 304 U.S. 64, 78 (1938). "Federal courts, unlike state courts, are not general common-law courts and do not possess a general power to develop and apply their own rules of decision." *City of Milwaukee*, 451 U.S. at 312; *see Texas Indus., Inc. v. Radcliff Materials, Inc.*, 451 U.S. 630, 640 (1981). Thus, even when federal courts have "express congressional authorization to devise a body of [federal common] law directly," *Sosa*, 542 U.S. at 726, any substantive rights must stem from an Act of Congress.

For example, this Court in *Mertens v. Hewitt Associates*, 508 U.S. 248 (1993), held that, even though Congress authorized the development of federal common law to interpret ERISA, 29 U.S.C. § 1001 *et seq.*, federal common law could not form the basis of a private right of action to enforce ERISA for non-fiduciaries because the Act did not affirmatively authorize such a suit. *Id.* at 255 & n.5. The Court in *Texas Industries, Inc. v. Radcliff Materials, Inc.*, 451 U.S. 630 (1981), similarly rejected a common law remedy of contribution under the Sherman Act, 15 U.S.C. § 1, because the Court found no affirmative indication that "Congress intended courts to have the power to alter or supplement the remedies enacted." *Id.* at 645. Likewise, Congress in the 340B Act

concededly did not provide for enforceable rights on behalf of 340B entities.

Further, where Congress has "occupied the field through the establishment of a comprehensive regulatory program supervised by an expert administrative agency," private remedies are limited to those enacted by Congress. *City of Milwaukee*, 451 U.S. at 317; *Middlesex Cnty. Sewerage Auth. v. Nat'l Sea Clammers Assoc.*, 453 U.S. 1, 21-22 (1981); *Nw. Airlines, Inc.*, 451 U.S. at 93-94. Thus, "once Congress addresses a subject . . . the task of the federal courts is to interpret and apply statutory law, not to create common law." *Nw. Airlines Inc.*, 451 U.S. at 95, n.34. "Although a federal court may disagree with the regulatory approach taken by the agency with responsibility . . . under the Act, such disagreement alone is no basis for the creation of federal common law." *City of Milwaukee*, 451 U.S. at 323. As discussed, private suits by 340B entities to enforce the manufacturers' drug-pricing obligations would seriously disrupt two massive, complex, and comprehensive drug-pricing programs.

2. Because Congress did not authorize a private right of action under the 340B Act, the County errs in relying 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). Br. in Opp. 4-5. Those decisions address a choice of law question—whether federal or state law should govern the construction of a contract where the federal government is a party or the contract otherwise implicates federal interests. *See Boyle v. United Techs. Corp.*, 487 U.S. 500, 512 (1988) (tort action governed by federal law); *Miree v. DeKalb Cnty.*, 433 U.S. 25, 29 (1977) (third-party beneficiary action governed by

state law). Those decisions do not address the threshold validity of a private right to sue.

Moreover, the plaintiff in *Jackson* 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."). *Jackson* makes clear that where a statute is involved, *congressional intent* is controlling. *Id.*; *see Empire Healthchoice Assurance, Inc. v. McVeigh*, 547 U.S. 677, 694-95 (2006). No decision of this Court supports the proposition that where Congress declines to create a cause of action, a court may use federal common law to create one anyway.

CONCLUSION

The judgment of the court of appeals should be reversed.

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