Supreme Court, U.S.
FILED

No. 09- 091273 APR 21 2010

OFFICE OF THE CLE

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.; and 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

PETITION FOR A WRIT OF CERTIORARI

LISA S. BLATT
Counsel of Record
JEFFREY L. HANDWERKER
ROBERT A. SCHWARTZ
ARNOLD & PORTER LLP
555 12th Street N.W.
Washington, DC 20004
(202) 942-5000
Lisa.Blatt@aporter.com

Counsel for All Petitioners for Purposes of this Petition

Blank Page

QUESTION PRESENTED

Section 340B of the Public Health Service Act, 42 U.S.C. § 256b, imposes a ceiling price that limits the prices that drug manufacturers may charge for drugs sold to specified health care facilities and entities, known as 340B entities. Section 340B requires 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(1)(10), 1396r-8(a)(1) & (b)(1)(A).

In the decision below, the Ninth Circuit held that the more than 2,700 covered 340B entities within the territory covered by the circuit 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. In direct conflict with the decisions of the Second, Sixth, and Tenth Circuits, the Ninth Circuit held that, notwithstanding the absence of a private right of action under the Act, a plaintiff may circumvent congressional intent under a federal common law claim that the plaintiff is 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 simply because the statutory requirement sought to be enforced is embodied in a contract.

RULE 14.1 STATEMENT OF CORPORATE DISCLOSURES

1) Astra USA, Inc., AstraZeneca Pharmaceuticals LP, and Zeneca Inc.

Astra USA, Inc., AstraZeneca Pharmaceuticals LP, and Zeneca Inc. disclose that they are indirect, wholly owned subsidiaries of AstraZeneca PLC, a publicly held corporation.

2) Aventis Pharmaceuticals Inc. and ZLB Behring LLC.

Aventis Pharmaceuticals Inc. is an indirect subsidiary of sanofi-aventis, a French corporation that is publicly traded on the Paris and New York exchanges. No publicly held company owns more than 10% of the stock of Aventis Pharmaceuticals Inc.

ZLB Behring LLC is a wholly-owned subsidiary of ZLB Bioplasma HK Limited, a Hong Kong company. ZLB Behring LLC's ultimate parent is CSL Limited, a publicly held Australian company with shares issued on the Australian Stock Exchange.

3) Bayer Corporation.

Bayer AG, a publicly held corporation headquartered in Leverkusen, Germany, is the parent corporation of Bayer Corporation, one of the appellees in this action. There is no publicly held corporation that owns 10% or more of Bayer AG's stock.

4) Bristol-Myers Squibb Company.

Bristol-Myers Squibb Company makes the following Corporate Disclosure Statement:

i) Bristol-Myers Squibb Company has no parent corporation.

ii) No publicly held company owns 10% or more of the stock of Bristol-Myers Squibb Company.

5) Merck & Co., Inc.

On November 3, 2009, "Schering-Plough Corporation" changed its name to Merck & Co., Inc. Merck & Co., Inc. states that (i) it has no parent company and (ii) there is no publicly held corporation owning 10% or more of its stock.

6) Pfizer Inc.

Pfizer Inc. makes the following Corporate Disclosure Statement:

i) Pfizer Inc. has no parent corporation.

ii) No publicly held company owns 10% or more of the stock of Pfizer Inc.

7) SmithKline Beecham Corp.

SmithKline Beecham Corp., now known as GlaxoSmithKline LLC, and which does business under the name GlaxoSmithKline, discloses that it is owned, through several levels of wholly owned subsidiaries, by GlaxoSmithKline plc, a publicly held English limited company. To the knowledge of GlaxoSmithKline LLC, none of the shareholders of

GlaxoSmithKline plc owns beneficially 10% or more of its outstanding shares.

8) TAP Pharmaceutical Products Inc.

TAP Pharmaceutical Products Inc. hereby discloses that on May 1, 2008 TAP Pharmaceutical Products Inc. became a wholly-owned subsidiary of Takeda America Holdings, Inc. On July 1, 2008, TAP Pharmaceutical Products Inc. merged into Takeda Pharmaceuticals North America, Inc., which is a wholly-owned subsidiary of Takeda America Holdings, Inc.

9) Wyeth, Inc. and Wyeth Pharmaceuticals Inc.

Wyeth and Wyeth Pharmaceuticals Inc. provide the following corporate disclosure:

i) Pfizer Inc. is the ultimate parent corporation of Wyeth LLC (sometimes identified as Wyeth Inc.). Wyeth Pharmaceuticals Inc. is a wholly owned subsidiary of Wyeth LLC.

ii) Pfizer Inc. owns ten percent (10%) or more of Wyeth LLC's stock.

iii) Wyeth LLC is not a party to any merger agreements with publicly held corporations at this time.

TABLE OF CONTENTS

TABLE OF CONTENTS OF APPENDICES

TABLE OF AUTHORITIES

CASES

STATUTES

OTHER AUTHORITIES

Blank Page

OPINIONS BELOW

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

JURISDICTION

The court of appeals' decision was entered on December 9, 2009. App., *infra*, 1a. A petition for rehearing was denied on February 11, 2010. App., *infra*, 125a. This Court's jurisdiction is invoked 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 App., *infra*, 127a-164a.

INTRODUCTION AND SUMMARY

The Medicaid Act requires all drug manufacturers whose outpatient drugs are covered by Medicaid to enter into contracts with the Secretary of Health and Human Services (HHS). Those agreements are known as Medicaid Rebate Agreements, and under them the manufacturers agree to provide drug rebates to States. Section 340B of the Public Health Service Act requires the same drug manufacturers to enter into a separate contract with the Secretary, known as the Pharmaceutical Pricing Agreement ("PPA"), under which the manufacturers agree to provide deeply discounted prices to certain health care providers and entities referred to as "340B entities." The Medicaid Act specifies the amount of rebates owed to States under the Medicaid program,

and the 340B Act specifies the formula for the ceiling prices that apply to purchases by 340B entities. Both the Medicaid rebate amounts and the Section 340B ceiling prices are based on the drug manufacturers' Average Manufacturer Price ("AMP") and Best Price as prescribed by the Medicaid Act. 42 U.S.C. §§ 256b, 1396r-8. Those statutory requirements can be enforced by the Secretary, but there is no provision—express or implied—for enforcement by any private parties.

The Ninth Circuit, in the decision below, held that federal common law confers on 340B entities the right to sue to enforce the statutory requirement that drug manufacturers accurately report AMP and Best Price 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 implied right of action to enforce the statutory requirement, 340B entities have a federal common law claim for breach of contract as third-party beneficiaries under the agreements between manufacturers and the Secretary under the 340B Act. The court of appeals 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. App., *infra*, 3a, 8a, 29a.

The Ninth Circuit's decision deepens an existing 5-3 circuit conflict on whether the absence of an implied right of action precludes reliance on a common law breach of contract claim to enforce the requirements of the statute. The Ninth Circuit's recognition of a common law claim directly conflicts with the decisions the Second, Sixth, and Tenth Circuits, which have squarely held that the absence of an implied private right of action under a statute forecloses common law third-party beneficiary

claims. *Grochowski v. Phoenix Constr.*, 318 F.3d 80 (2d Cir. 2003); *Hodges v. The Atchison, Topeka & Santa Fe Ry. Co.*, 728 F.2d 414 (10th Cir. 1984); *Hoopes v. Equifax, Inc.*, 611 F.2d 134 (6th Cir. 1979). By contrast, five other circuits, including the Ninth Circuit, have held that common law third-party-beneficiary principles may provide a private right to enforce a statutory requirement even in the absence of an implied right under the statute. *Dewakuku v. Martinez*, 271 F.3d 1031 (Fed. Cir. 2001); *D'Amato v. Wisconsin Gas Co.*, 760 F.2d 1474 (7th Cir. 1985); *Nguyen v. The U.S. Catholic Conf.*, 719 F.2d 52 (3d Cir. 1983); *Perry v. Housing Auth. of Charleston*, 664 F.2d 1210 (4th Cir. 1981); *Falzarano v. United States*, 607 F.2d 506 (1st Cir. 1979). The question presented is of paramount importance and recurs frequently under a number of federal statutes, including the Medicaid Act and 340B Act, that implement congressional mandates through contracts between the United States and private parties.

The court of appeals' recognition of a private right of action to enforce the 340B Act's drug pricing provisions has immediate and profoundly adverse consequences on the administration of both the drug rebate program under the Medicaid Act and the drug ceiling price program under the 340B Act. Both programs use the same drug pricing components and employ contracts to implement the statute. A private right of action under the Section 340B program would permit potentially 14,500 entities nationwide (of which approximately 2,700 reside in states within the Ninth Circuit), that spend $4 billion annually on outpatient drugs, to sue hundreds of drug manufacturers based on the manufacturers' pricing and sales data for more than 35,000 pharmaceutical products sold pursuant to those federal programs. *See infra*, pp. 5-7, 22.

The Ninth Circuit's decision ignores Congress's considered judgment that a private right of action would directly interfere with the government's ability to administer both the Medicaid Drug Rebate and Section 340B ceiling price programs. The Executive Branch also advised the Ninth Circuit that a private suit would disrupt its administration of *both* programs and risk the imposition of inconsistent obligations on the manufacturers whose sales HHS is charged with regulating. The court's ruling also inflicts immediate, enormous, and costly burdens on drug manufacturers that are now exposed to suits that neither they nor the government imagined. This Court's intervention is warranted to prevent the court of appeals' decision from wreaking havoc on these two critical federal health care programs.

The Ninth Circuit's holding also is patently wrong. "There is no general federal common law." *Erie R. Co. v. Tompkins*, 304 U.S. 64, 78 (1938). Only Congress has the authority to create a private right of action to enforce a statutory obligation, and the incorporation of that obligation into a contract does not create a right of action to enforce the underlying statute. Under no circumstances can federal common law create a private right to enforce a statute that does not itself supply that right either expressly or impliedly. *Alexander v. Sandoval*, 532 U.S. 275, 287 (2001); *Virginia Bankshares v. Sandberg*, 501 U.S. 1083, 1102 (1991); *Wheeldin v. Wheeler*, 373 U.S. 647, 651 (1963). The Ninth Circuit's disregard of those settled principles calls out for this Court's correction.

STATEMENT

A. STATUTORY FRAMEWORK

This case arises under two interrelated federal programs for outpatient drugs—the Medicaid Drug

Rebate Program and the Section 340B Drug Ceiling Price Program. The Medicaid Act requires drug manufacturers to calculate and report the AMP and Best Price for Medicaid covered drugs, which in turn are used to calculate the ceiling price for Section 340B drugs. Neither program provides a private right of action to enforce the statutory drug pricing requirements.

1. The Medicaid Drug Rebate Program

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" under which manufacturers pay rebates to States. 42 U.S.C. § 1396b(i)(10); *id.* § 1396r-8(a)(1), (b)(1)(A). Approximately 550 manufacturers have entered into rebate agreements with the Secretary covering more than 35,000 drugs, and manufacturers in 2002 paid approximately $5.6 billion in rebates to States.[1]

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 a "single source drug" or an "innovator multiple source drug," the rebate due on each unit paid under a state plan is typically either (a) the

---

[1] Centers for Medicare and Medicaid Services, Medicaid Drug Rebate Program Overview, http://www.cms.gov/MedicaidDrugRebateProgram/; UNITED STATES GOVERNMENT ACCOUNTABILITY OFFICE, MEDICAID DRUG REBATE PROGRAM, INADEQUATE OVERSIGHT RAISES CONCERNS ABOUT REBATES PAID TO STATES 1 (Feb. 2005), *available at* http://www.gao.gov/new.items/d05102.pdf.

difference between the AMP and the manufacturer's Best Price, defined as the lowest price available (with some exceptions) from the manufacturer to any private purchaser or governmental entity within the United States, or (b) 15.1% of the AMP, whichever is greater. *Id.* § 1396r-8(c)(1)(A), (B) & (C) & (c)(2). For other drugs, the rebate is 11% of the AMP. *Id.* § 1396r-8(c)(3).

The Act requires manufacturers to report quarterly to the Secretary the AMP and Best Price for each of its "covered outpatient drugs." *Id.* § 1396r-8(b)(3)(A). 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). For the relevant period in this case, the Act also provided that "[n]otwithstanding any other provision of law, information disclosed by manufacturers * * * 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." *Id.* § 1396r-8(b)(3)(D).

2. 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 to offer discounted drug prices to certain hospitals and clinics, so-called "safety net providers," that receive federal funds ("340B entities"). In 2005 alone, 340B entities spent $4 billion for drugs covered by the Section 340B program.[2] Over 800

---

[2] Oversight and Administration of the 340B Drug Discount Program: Improving Efficiency and Transparency, Hearing Before the H. Comm. on Energy and Commerce Subcomm. on

drug manufacturers participate in the Section 340B program.[3]

In order for outpatient prescription drugs to be covered by Medicaid, drug manufacturers must sign an agreement consenting to the ceiling price set by the 340B Act. 42 U.S.C. § 1396r-8(a)(1), (5). Incorporating the same AMP and Best Price pricing methodology of the Medicaid Rebate Program, the 340B Act provides that "[t]he Secretary shall enter into an agreement with each manufacturer of covered drugs under which" the manufacturer may not charge to any 340B entity an amount that exceeds "the average manufacturer price for the drug under title XIX of the Social Security Act [42 U.S.C. § 1396 *et seq.*] in the preceding calendar quarter, reduced by [a] rebate percentage." *Id.* § 256b(a)(1). The "rebate percentage" is defined 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." *Id.* § 256b(a)(2)(A)(ii). Because of this ceiling price, 340B entities receive significant discounts.

Oversight and Investigations 1 (Dec. 15, 2005) (testimony of Stuart Wright, Deputy Inspector General for Evaluation and Inspections Office of Inspector General, U.S. Department of Health and Human Services), *available at* http://archives.energycommerce.house.gov/reparchives/108/Hearings/12152005hearing1739/Wright.pdf.

[3] 2010 Quarter 2 Statistics for 340B Covered Entities (Apr. 1, 2010), *available at* ftp://ftp.hrsa.gov/bphc/pdf/opa/stats_2010_QTR_2.pdf.

As instructed by the Act, Section 340B's ceiling price requirements are set forth in a Pharmaceutical Pricing Agreement, which is a form contract prepared by HHS's Health Resources and Services Administration (HRSA). App., *infra*, 165a-181a. The PPA expressly incorporates by reference the manufacturer's statutory drug pricing obligations to report AMP and Best Price 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 (¶ 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 Secretary "may initiate [an] informal dispute resolution process." *Id.* at 174a (¶ IV(c)). If the Secretary's allegation proves well founded, "the Secretary may require the Manufacturer to reimburse the entity for discounts withheld and can also terminate" the PPA. *Id.* The PPA provides that the agreement "shall be construed in accordance with Federal common law." *Id.* at 180a (¶ VII(g)).

B. PROCEEDINGS BELOW

1. Petitioners are nine of the largest pharmaceutical manufacturers in the world. They were sued in this putative class action by the County of Santa Clara, California, on behalf of itself and other California counties that have responsibility for funding public hospitals, affiliated pharmacies, community health centers, and other public healthcare providers that fund the costs for prescription drugs through the Section 340B program. The County initially filed suit in state court, alleging that petitioners violated the ceiling

prices set forth in Section 340B. 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 breach of contract claim alleging that "[a]s the intended beneficiaries of the PPA," the class members were "entitled to damages they sustained as a result of [the petitioners'] breach of contract." Second Am. Compl. ¶ 104.

After again dismissing the state law claims, the district court dismissed the breach of contract claim under the PPAs, holding that neither the statute nor the PPA reflects an intent to bestow on private parties the right to sue to enforce the Act's pricing requirements. App., *infra*, 119a. With respect to the plaintiff's argument that class members are intended beneficiaries of the PPA, the court observed that it "strains credulity" to suggest that petitioners would have agreed to face the threat of "a crushing number of lawsuits" from "more than 12,000 covered entities."[4] *Id.* at 116a. The County appealed the dismissal of the breach of contract claim under the PPA.

2. The Ninth Circuit reversed and held that "federal common law" provides a breach of contract action for 340B entities to enforce the Act's drug pricing provisions as incorporated into the PPA. App., *infra*, 38a, 50a, 54a, 55a. In so holding, the court of appeals held that 340B entities "are intended

---

[4] Since the district court's decision, the number of 340B entities has increased significantly to more than 14,500 nationwide. Additionally, the recently enacted Patient Protection and Affordable Care Act further increases the number of eligible 340B entities. *See infra*, pp. 22-23.

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 court of appeals reasoned that "the right to sue inheres in one's status as an intended beneficiary." *Id.* at 39a. The Ninth Circuit also observed 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 itself was somehow erroneous." *Id.* at 57a.

On remand, the district court interpreted the court of appeals' statement that the suit involved only the prices "reported to the Secretary" to bar disclosure of the drug manufacturers' underlying pricing data and the methods by which petitioners derived the AMP and Best Price figures reported to the Secretary. App., *infra*, 80a-81a. On interlocutory appeal, the Ninth Circuit invited the views of the Secretary of HHS concerning whether the case should be stayed and referred to the Secretary under the doctrine of primary jurisdiction. *See* 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 (9th Cir. Oct. 27, 2009) ("Gov't Br.").

3. In response to the court of appeals' invitation, the United States, setting forth the considered judgment of the Secretary of HHS, 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 signatories." *Id* at *9, *12. The agency 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 AMP and Best Prices. *Id.* at *12; *see* 42 U.S.C. 1396r-8(b)(3)(D).

The government also explained that the Medicaid Drug Rebate program has conferred considerable discretion on drug manufacturers to make reasonable estimates in calculating the AMPs and Best Prices under the Medicaid Act, which are in turn used to calculate ceiling prices under the 340B Act. Gov't Br., 2009 WL 4089524, at *6. As a result, the government explained that the recognition of a private right of action to enforce the Acts' pricing requirements would interfere with the agency's exclusive responsibility to administer both programs on a nationwide, uniform basis. *Id.* at *11 ("allowing suits like this would threaten the orderly operation of *both* programs" (emphasis in original)).

The government further explained that the programs create conflicting incentives for beneficiaries under the respective programs. The government thus observed that while relatively high AMPs generally increase the price that manufacturers may charge 340B entities (to the *detriment* of those 340B entities), high AMPs also increase the manufacturers' much larger rebate obligations to the States (which *benefits* the Medicaid program). *Id.* at *15. Those conflicting incentives, the government observed, highlight the need to leave the administration and enforcement of the 340B Act and Medicaid Act where Congress placed it, *i.e.,* with the Secretary of HHS, who has the expertise to resolve complex issues of pricing

methodology and difficult issues of statutory interpretation under both programs. *Id.*

4. 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 to only the drug pricing information reported to the government. App., *infra*, 1a-29a. Although the court of appeals had invited the agency's participation, the superseding decision neither discussed nor deferred to the agency's express objection to the Ninth Circuit's recognition of a common law right of action under the 340B Act.

REASONS FOR GRANTING THE PETITION

In a decision with dramatic and sweeping consequences, the Ninth Circuit has held that federal common law creates out of whole cloth a private right of action for several thousand public and private health care facilities and providers to sue drug manufacturers whose outpatient drugs are covered by Medicaid. This Court should review and reverse the Ninth Circuit's decision for three reasons.

First, the court of appeals' holding squarely conflicts with the decisions of other courts of appeals. The Ninth Circuit premised its creation of a cause of action to enforce a statute that does not itself confer one on the common law principle that "intended beneficiaries" of a statutory contract may sue to enforce the statutory requirements embodied in the contract. While other circuits have endorsed that approach, the Second, Sixth, and Tenth Circuits in sharp contrast have held that such a suit is an impermissible end-run around the absence of an implied private right of action under the statute and therefore have rejected the very approach embraced by the Ninth Circuit in this case.

Second, the court of appeals' creation of a private right of action for 340B entities to enforce the drug pricing provisions of *both* the 340B Act and the Medicaid Act has vast implications and risks disrupting the approximately $30 billion Medicaid program for outpatient prescription drugs. The statutes contain no private right of action; instead, they confer on the Secretary considerable discretion to apply agency expertise and administer a complex statutory framework. A private right of action subverts congressional intent and perilously interferes with the government's ability to administer these massive nationwide programs. Private suits also risk the imposition of conflicting obligations and of unjustified burdens on drug manufacturers.

Third, the court of appeals' recognition of a private right of action under the common law jettisons the bedrock principles that "[t]here is no general federal common law," *Erie R. Co. v. Tompkins*, 304 U.S. 64, 78 (1938), and that only Congress can create private rights of action to enforce a statute, *e.g.*, *Alexander v. Sandoval*, 532 U.S. 275 (2001). In striking disregard of those precedents, the court of appeals concluded that the burden was on *Congress* to *abrogate* a pre-existing federal common law right of action for breach of contract. The Ninth Circuit's invocation of federal common law to confer a right of action where none exists by statute reflects a serious judicial usurpation of legislative power.

I. THE NINTH CIRCUIT'S DECISION DEEPENS AN ENTRENCHED CIRCUIT CONFLICT

In holding that federal common law authorizes a cause of action to enforce a statutory requirement, the Ninth Circuit deepened a conflict in the circuits on the question of whether the common law may ever

trump the absence of an express or implied private right of action. Three courts of appeals, in sharp contrast to the Ninth Circuit, have answered that question in the negative, holding that judge-made law cannot provide a right of action that Congress did not authorize. A 5-3 circuit split has developed over decades and is firmly entrenched. This case is also a perfect vehicle to resolve an issue that recurs routinely under a vast variety of federal programs administered through contracts between federal agencies and private parties.

A. The Circuits Are Deeply Divided Over The Validity Of A Common Law Third-Party Beneficiary Claim To Enforce Statutory Mandates Incorporated Into A Contract

1. The Ninth Circuit's holding that federal common law forms the basis of a private right of action to enforce an Act of Congress squarely conflicts with the decisions of three circuits that have rejected the validity of such an action. The Second Circuit in *Grochowski v. Phoenix Construction*, 318 F.3d 80 (2d Cir. 2003), held that where a federal statute provides no private right of action, it follows *a fortiori* that a third party cannot enforce the statute by asserting a common law claim as an intended beneficiary of a contract embodying the statutory requirement. *Id.* at 86. In *Grochowski*, workers sued building contractors operating federally funded construction contracts for the contractors' alleged failure to pay the wages required by the Davis-Bacon Act. The court of appeals held that circuit precedent establishing the absence of a private right of action under Davis-Bacon was likewise dispositive of the workers' common law claims that they were third-party beneficiaries of the contract, which had incorporated the Act's wage requirements. *Id.*

In contrast with the Ninth Circuit here, the Second Circuit reasoned that, when there is no statutory private right of action, such a right cannot be pursued simply by recasting it as a contract claim under the common law. *Id.* at 85-86. The court explained that common law claims "are indirect attempts at privately enforcing the prevailing wage schedules contained in the [Act]," and would interfere with congressional intent "to the same extent as would a cause of action directly under the statute." *Id.* at 86 (internal quotation marks omitted). Thus, the court concluded that 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.*

The Sixth Circuit followed the same rule in *Hoopes v. Equifax, Inc.*, 611 F.2d 134 (6th Cir. 1979). In that case, a discharged employee sued his former employer for disability discrimination in violation of the Rehabilitation Act, arguing that he was "entitled to challenge his dismissal because he was a third party beneficiary under a contract between his employer and the United States Government." *Id.* at 135. The Sixth Circuit affirmed summary judgment against the employee, explaining that the Act "does not authorize a private cause of action in the courts." *Id.*

The Tenth Circuit followed *Hoopes* in *Hodges v. The Atchison, Topeka & Santa Fe Railway Co.*, 728 F.2d 414 (10th Cir. 1984) In *Hodges*, a discharged railroad worker sued his former employer claiming wrongful discharge, also in violation of the Rehabilitation Act, arguing both that the statute contains an implied private right of action, *id.* at 415, and that he was "a third-party beneficiary" to the railroad's "federal contracts which prohibit discrimination against the handicapped, pursuant to"

the Act, *id.* at 416. The Tenth Circuit analyzed the issue under *Cort v. Ash*, 422 U.S. 66 (1975), and held that "neither the legislative history nor the Act in general" could support a private right of action. *Hodges*, 728 F.2d at 415. The court disallowed the "third-party beneficiary" claim for the same reasons, stating that "[t]his is but another aspect of the implied right of action argument." *Id.* at 416 (citing the Sixth Circuit's decision in *Hoopes*).

2. Departing from those holdings are the decisions of five circuits, including the Ninth Circuit, that have held that, notwithstanding the absence of an implied right of action, a statutory requirement embodied in a contract may be enforced by a "third party beneficiary" claim for breach of contract. For instance, in *Dewakuku v. Martinez*, 271 F.3d 1031 (Fed. Cir. 2001), the Federal Circuit entertained a third-party beneficiary common law claim for breach of contract even though the court held that there was no private right of action under the statute at issue, the Indian Housing Act of 1988. *Id.* at 1037. The court separately examined the common law question because the statutory requirement sought to be enforced had been incorporated into a contract with the government. *Id.* at 1040-41. The court held that the "test for intended third party beneficiary status is whether the contract reflects the intent of the parties to the contract to benefit the third party." *Id.* at 1041.

Similarly, the Seventh Circuit in *D'Amato v. Wisconsin Gas Co.*, 760 F.2d 1474 (7th Cir. 1985), after noting that "no private right of action arises under Section 503" of the Rehabilitation Act, nonetheless held that federal common law could supply a cause of action because the two doctrines were distinct. *Id.* at 1478. The court reasoned that although congressional intent controls the question of a statutory private right of action, a common law

claim rests on "whether the parties" to the contract "intended to confer an actionable right." *Id.* at 1478-79. Other circuits have similarly held that a third party beneficiary claim may be pursued if the "common law" elements are met, even in the absence of an implied right of action. *Nguyen v. The U.S. Catholic Conf.*, 719 F.2d 52 (3d Cir. 1983) (Refugee Assistance Act of 1962); *Perry v. Housing Auth. of Charleston*, 664 F.2d 1210, 1217-18 (4th Cir. 1981) (Housing Act of 1937, 42 U.S.C. § 1437, *et seq.*); *Falzarano v. United States*, 607 F.2d 506, 511 (1st Cir. 1979) (National Housing Act, 12 U.S.C. § 1715L).

B. The Circuit Split Warrants This Court's Intervention

1. This Court's intervention is warranted to resolve the circuit conflict and bring uniformity to an important and recurring area of federal law. There are few questions of federal law as worthy of this Court's attention as the power of federal courts to create causes of action from whole cloth without authority from Congress. The court of appeals' decisions that have confronted the question have arisen under a variety of different public welfare programs that are administered through contracts incorporating statutory requirements. *Supra*, pp. 14-17. And despite the recurring nature of the issue under a wide variety of federal assistance programs, this Court has never addressed the precise issue of whether a common law breach of contract claim exists to enforce an Act of Congress that is implemented through contracts even where the Act does not contain an implied right of action.

"Because of the frequency with which the government employs contracts as instruments of federal policy, recent years have been marked by a wave of cases involving third-party beneficiary claims under contracts with agencies of the federal government." Note: *Who's Watching the Watchdogs?*

103 Colum. L. Rev. 893, 918 (2003). Third party beneficiary claims frequently arise because they serve as a means to evade this Court's limitations on the ability of courts to imply causes of action. As one commentator has observed, "a third party beneficiary claim is more likely to prevail than an [implied right of] action on the statute." Anthony Jon Waters, *The Property in the Promise: A Study of the Third Party Beneficiary Rule*, 98 HARV. L. REV. 1109, 1176 and 1178 (1985); *see also* Note: *Third Party Beneficiary & Implied Right of Action Analysis: The Fiction of One Governmental Intent*, 94 YALE L.J. 875, 875 (1985) (explaining that because of "the Supreme Court's increasingly restrictive view of implied rights of action," "in recent years the number of third-party claims arising from welfare-related public contracts has grown significantly" (footnote omitted)); Note: *The Power Behind the Promise: Enforcing No Child Left Behind to Improve Education*, 45 B.C. L. REV. 667 (2004) (urging litigants to sue as third party beneficiaries to enforce the No Child Left Behind Act of 2001).

The issue thus regularly arises in district courts under numerous federal laws. *See, e.g., D.G. v. Henry*, 594 F. Supp. 2d 1273, 1281 (N.D. Okla 2009) (Adoption Assistance and Child Welfare Act of 1980); *Rogers v. U.S. Army*, NO. H-06-1389, 2007 U.S. Dist. LEXIS 30056, at *38 (S.D. Tex. Apr. 23, 2007) (Davis-Bacon Act); *Sabeta v. Baptist Hosp. of Miami, Inc.*, 410 F. Supp. 2d 1224, 1233-34 (S.D. Fla 2005) (Section 501(c)(3) of the tax code); *Charlie & Nadine H. v. Whitman*, 83 F. Supp. 2d 476, 502 (D.N.J. 2000) (Adoption Assistance Act and Child Abuse Prevention and Treatment Act); *Brug v. National Coal. for the Homeless*, 45 F. Supp. 2d 33, 41 (D.D.C. 1999) (affirmative action guidelines for government contractors); *In re Lake States Commodities, Inc.*, 936 F. Supp. 1461, 1470 & n.13 (N.D. Ill 1996) (Commodities Exchange Act § 13(a)).

Finally, in addition to the Medicaid drug rebate and 340B ceiling price programs, other important health care programs are administered through contract mechanisms. *See, e.g.*, 38 U.S.C. § 8126(a) (Department of Veterans Affairs health care program); 10 U.S.C. § 1074g(f) (DoD "TRICARE" retail pharmacy benefit); 42 U.S.C. § 1395w-101(a) (Medicare outpatient prescription drug benefit "coverage gap rebate program," created by Patient Protection and Affordable Care Act).

2. The conflict in the circuits is mature and ripe for this Court's review. The Second, Sixth, and Tenth Circuits have had no difficulty rejecting a common law claim as the source of a cause of action that Congress itself did not provide. The First, Third, Fourth, Ninth, and Federal Circuits, however, have held that the federal common law, independent of a statute, may confer a private right of action. Indeed, in *D'Amato*, the Seventh Circuit criticized the Sixth Circuit's decision in *Hoopes* for "failing" "to distinguish between" the "determination of whether a private right of action arises directly under the statute" and whether a common law claim may be brought under a "third party beneficiary theory." 760 F.2d at 1478 n.3 & n.4.

Moreover, although the Ninth Circuit attempted to distinguish the Second Circuit's decision in *Grochowski*, its reasoning actually reinforces the fundamental division in the circuits. The Ninth Circuit reasoned that there was no basis for a common law remedy in *Grochowski* because the government had promulgated regulations creating administrative remedies for violations of the Davis Bacon Act. App., *infra*, 24a-27a. By contrast, because 340B entities had no statutory or administrative remedies to invoke against drug manufacturers, the Ninth Circuit deemed that it had the authority to create a judicial remedy that would

not be adding a remedy over and above what the statute provided. *Id.*

The court's analysis completely misses the point of *Grochowski* that recognition of a common law claim is an "end run" around Congress's decision not to provide a private right of action. The existence of administrative remedies may be relevant to whether there is an implied right of action in the first place, but the absence of an implied right of action ends the inquiry, including any examination of whether a judicial remedy would supplant or supplement an administrative remedy authorized by Congress. The Ninth Circuit thus seriously erred in relying on the absence of an administrative remedy as a basis for imposing a judicial remedy. Creating a judicial remedy where Congress provided none condones precisely the end-run rejected in *Grochowski*. Because only this Court can resolve the fundamental division in the circuits on the threshold propriety of a common law cause of action in the absence of an express or implied right under the statute, this Court's intervention is warranted.

3. This case represents an excellent vehicle for this Court to resolve the conflict in the circuits. The issue on which the circuits are divided is cleanly presented in this case, and there is no need for further factual development. Moreover, no proceedings on remand would bear on the Court's disposition of the case. Although the court of appeals left open the possibility that deferral to the Secretary might be warranted under the doctrine of primary jurisdiction, App., *infra*, 27a-29a, deferral would not lead to the dismissal of the suit, *i.e.*, the result that would be compelled under the rule adopted by the Second, Sixth, and Tenth Circuits. Moreover, the court of appeals' decision announces a broad rule with far-reaching implications and already has caused immediate harm in this case. *See infra*, pp.

23-24. There is no reason for this Court to wait to resolve a recurring and important issue that has long divided the circuits.

II. THE NINTH CIRCUIT'S DECISION SERIOUSLY DISRUPTS THE MEDICAID DRUG REBATE AND 340B CEILING PRICE PROGRAMS

A. The Court of Appeals' Recognition Of A Private Right Of Action Under The Statutory Drug Pricing Provisions Warrants Review

1. The Ninth Circuit's recognition of a private right of action to enforce both the Medicaid Act and 340B Act pricing provisions warrants this Court's review. Both the Medicaid drug rebate program and the Section 340B ceiling price program are administered though contracts incorporating the statutory requirement that drug manufacturers calculate and accurately report to the Secretary AMP and Best Price information. Whether there is a common law private right of action against drug manufacturers to challenge their drug pricing obligations under two major health care Acts of Congress is an issue of abiding national importance.

The Ninth Circuit's holding directly impacts a government financial assistance program that is massive in size and scope. In fiscal year 2002 alone, Medicaid drug expenditures totaled $29.3 billion. In 2002, drug manufacturers paid Medicaid rebates to States totaling $5.6 billion. *See supra*, n.1. In 2005, 340B entities spent $4 billion on covered outpatient drugs. *See supra*, n.2. More than 800 drug manufacturers report AMP and Best Price data for

over 35,000 pharmaceuticals. *See supra*, nn. 1 & 3. Over 14,500 entities are currently covered by Section 340B, over 2,700 of which are located in the States within the Ninth Circuit alone. *See supra*, n.3.[5]

Moreover, the recent health care reform legislation significantly expands the categories of 340B entities, and thus the potential plaintiffs that may file suit under the rule of the Ninth Circuit. *See* Patient Protection & Affordable Care Act, Pub. L. No. 111-148, § 7101, 124 Stat. 119 (2010) (expanding the categories of eligible entities under the 340B Program to include certain children's hospitals, free standing cancer hospitals, critical access hospitals, rural referral centers, and sole community hospitals).

2. Given the sheer size and breadth of the Medicaid rebate program for which AMPs and Best Prices are calculated and reported, as well as the 340B ceiling price program in which AMPs and Best Prices are used to set ceiling prices, plaintiffs suing under a private right of action could seek to impose massive liability and burdens on drug manufacturers. This class action lawsuit is not an isolated incident. *See Central Ala. Comprehensive Healthcare, Inc. v. Aventis Pharm., Inc.*, 427 F. Supp. 2d 1129 (M.D. Ala. 2006) (putative nationwide class

---

[5] Health Resources and Services Administration, Office of Pharmacy Affairs Database, http://opanet.hrsa.gov/opa/Report/DailyReport.aspx (last visited Apr. 4, 2010); Health Resources and Services Administration, Office of Pharmacy Affairs Database, Covered Entity Data Extract, http://opanet.hrsa.gov/opa/CE/CEExtract.aspx (last visited Apr. 4, 2010).

action under Section 340B Program); *In re Pharm. Ind. Average Wholesale Price Litig.*, MDL No. 1456, 2007 WL 1051642 (D. Mass. Apr. 2, 2007) (suit by State and 42 counties as third party beneficiaries under rebate program); *In re Pharm. Ind. Average Wholesale Price Litig.*, 339 F. Supp. 2d 165 (D. Mass. 2004) (suit by county as third party beneficiary under rebate program). Forcing drug companies to defend such suits is wholly unwarranted, absent clear evidence that Congress authorized a cause of action under either Act.

Indeed, the mere pendency of a private party suit seeking to enforce statutory drug pricing requirements imposes enormous and unjustified burdens on drug manufacturers. For example, the suit here alleges that petitioners over a nine-year period miscalculated the AMP and the Best Price of covered outpatient drugs, causing 340B entities in California to pay a higher price for covered drugs than warranted under the 340B drug ceiling price program. The Medicaid Act requires manufacturers to calculate the AMP and Best Price based on *nationwide* sales transactions to all eligible purchasers. 42 U.S.C. § 1396r-8.

Petitioners in this case have thus been ordered to produce confidential and sensitive drug pricing and sales information on a national basis for hundreds of millions of drug sale transactions. App., *infra*, 74a-77a. The breadth and quantity of that information is breathtaking. For petitioner GlaxoSmithKline, for instance, the suit covers "more than 100 million [computer] data records per quarter" that sort and analyze data for the company's AMP and Best Price

calculations. Declaration of David Brown (Mar. 11, 2010) ¶ 9. That size and scope is typical for other manufacturers as well. *See, e.g.*, Declaration of Paul Le Compte ¶ 5 (Mar. 11, 2010) ("approximately 150 million sales records" for Pfizer); Declaration of Kathleen Dynan Black ¶ 8 (Mar. 11, 2010) ("over 30 million sales transactions" for Wyeth). The pendency of any litigation is a serious burden to any defendant, but this particular litigation, if allowed to proceed, involves burdens that vastly exceed the norm and thus makes immediate intervention by this Court particularly warranted.

B. The Ninth Circuit's Decision Disrupts Both The Medicaid Drug Rebate and 340B Ceiling Price Programs

1. The calculation of AMP and Best Price used to determine Medicaid rebates and 340B ceiling prices involves difficult and exceedingly complex questions of statutory interpretation, application, and calculation. *See* Gov't Br., 2009 WL 4089524, at *6. While the Secretary has issued approximately 80 informal guidance "releases" and regulations concerning drug price regulation, she has yet to resolve many outstanding interpretive and calculation issues. That regime has resulted in manufacturers' employing varying calculation methods. *Id.* The government's administration and enforcement of the statutory scheme should not be second-guessed by courts and juries deciding private suits challenging drug manufacturers' calculations of the AMP and Best Price for covered drugs. As the agency has concluded, "[a]llowing plaintiff's challenge would undermine HHS's role and

improperly shift the yardstick by which manufacturers' reports are judged." *Id.* at *9.

The damage wrought by the court of appeals' decision extends to the Medicaid Drug Rebate Program as well as the Section 340B Program. As discussed, the Section 340B Program expressly incorporates the drug pricing provisions of the Medicaid Drug Rebate Program. 42 U.S.C. § 256b(a) (incorporating by reference 42 U.S.C. 1396r-8). "[D]isputes over AMP and Best price are challenges to prices reported as part of the Medicaid Rebate Program." Gov't Br., 2009 WL 4089524, at *9. The government thus has concluded that a private right of action would "squarely implicate[] [HHS's] oversight of" Medicaid and would disrupt the operation of "*both* programs." *Id.* at *9, *11 (emphasis in original).

If not reversed, the Ninth Circuit's recognition of a private right of action seriously threatens to impose conflicting obligations on drug manufacturers under both the Medicaid drug rebate and 340B ceiling price programs, contrary to the exclusive authority Congress conferred on the government "to resolve issues for both programs at once." *Id.* at *15. The government explained to the Ninth Circuit that 340B entities have the incentive to allege that manufacturers overstated their AMP calculations, which, if reduced, would likely reduce 340B ceiling prices (to the advantage of the plaintiffs in this litigation)—but would also reduce the comparatively much larger Medicaid rebate payments to States.

Thus, States, under the Medicaid program, have the opposite incentive—to maintain the higher reported AMPs, which would increase the rebates the States receive:

> The problem is that, in some circumstances, challenges to an AMP calculation can have opposite effects on 340B entities and state Medicaid plans. In the 340B Program, a drug's ceiling price will be AMP minus [the unit rebate amount], giving covered entities an incentive to argue that AMP should be as low as possible—a lower AMP generally means a lower ceiling price. On the other hand, because states' rebates will often be a defined percentage of AMP . . . , states often have an incentive to argue that AMP figures should be higher.

Id. at *15. "Accordingly, if both 340B entities and states can bring separate suits over AMP calculations, there is a real danger that manufacturers could be subject to inconsistent obligations." *Id.* That risk is wholly unjustified when Congress did not intend to confer any private right of action to enforce the statutory scheme.

III. THE NINTH CIRCUIT'S DISREGARD OF THIS COURT'S JURISPRUDENCE WARRANTS REVIEW

The court of appeals' decision is patently erroneous. This class action seeks to enforce *statutory* requirements, *i.e.*, the drug pricing statutory formula for determining the AMP and Best Price under the Medicaid Act's drug rebate program

and the 340B Act's ceiling prices. The contract merely incorporates the Medicaid Act and 340B Act drug pricing obligations, App., *infra*, 170a-71a (PPA ¶¶ II(a)-(d)), and does not impose any additional pricing obligations. The County concedes that the breach of contract claim hinges on the allegation that petitioners charged more than the ceiling price permitted by Congress. Appellants' C.A. Br. 6 (Mar. 16, 2009); Third Am. Compl. (Dec. 23, 2008). Neither the Medicaid Act nor the 340B Act expressly or impliedly confers a private right of action. The court of appeals' erroneous creation of a new right of action under the guise of enforcing a contract merits this Court's correction.

A. The Federal Common Law Cannot Create A Private Right Of Action To Enforce A Statutory Requirement

1. "There is no general federal common law." *Erie 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 v. Illinois*, 451 U.S. 304, 312 (1981); *see Texas Indus., Inc. v. Radcliff Mat'ls, Inc.*, 451 U.S. 630, 640 (1981). And, to the extent that Congress has authorized courts to develop federal common law, such as under ERISA or the Sherman Act, it is elementary that federal common law is "subject to the paramount authority of Congress." *Northwest Airlines, Inc. v. Transport Workers Union of Am.*, 451 U.S. 77, 95 (1981).

Accordingly, this Court has repeatedly rejected attempts to graft common law rights and remedies onto federal statutes that do not provide them. For example, in *Mertens v. Hewitt Associates*, 508 U.S. 248 (1993), the Court held that federal common law could not form the basis of ERISA liability for non-fiduciaries because the Act did not affirmatively

authorize such a suit. *Id.* at 255 & n.5. Similarly, in *Texas Industries*, the Court rejected a common law claim for contribution under the federal antitrust statutes because the authority to create such a claim was within the exclusive province of Congress. 451 U.S. at 646.

2. The court of appeals' decision violates those settled principles. Indeed, the court concluded that the burden was on Congress to *displace* a general federal common law cause of action. The court thus reasoned that "§ 256 *does not abrogate* the cause of action ordinarily provided by the federal common law of contracts." App., *infra*, 24a n.16 (emphasis added). There is, however, no free-standing cause of action under the federal common law in favor of 340B entities that Congress must "abrogate." Rather, Congress must affirmatively authorize the cause of action.

That conclusion is not altered by the fact that the agreements at issue here "shall be *construed* in accordance with Federal common law." App., *infra*, 180a (¶ VII(g)) (emphasis added). All that provision does is to identify federal common law, as opposed to that of any specific State, as the source of law for interpretation of the document in the event a term is disputed by the parties to the agreement. It is well settled that federal common law principles govern the contractual obligations of the United States. *E.g.*, *Mobil Oil Expl. & Producing Se., Inc. v. United States*, 530 U.S. 604 (2000).[6]

---

[6] 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." App., *infra*, 8a n.5. The PPA by its terms, however, is governed by federal

Neither a government contract nor common law principles governing the parties' contractual obligations, however, may form the basis of a private right of action to enforce an act of Congress. *Erie* long ago established that federal common law is not a grant of judicial power to create new substantive rights. As the Court has emphasized, "recognition of any private right of action for violating a federal statute must ultimately rest on congressional intent to provide a private remedy." *Virginia Bankshares v. Sandberg*, 501 U.S. 1083, 1102 (1991); *see Wheeldin v. Wheeler*, 373 U.S. 647, 651 (1963) ("As respects the creation by the federal courts of common-law rights, it is perhaps needless to state that we are not in the free-wheeling days antedating *Erie*."). Likewise, any right by private parties to enforce the manufacturers' obligations under the Act's drug pricing provisions must stem from congressional authorization.

That principle cannot be circumvented simply by dressing the same claim up in breach of contract garb. For instance, in *United States v. Erika, Inc.*, 456 U.S. 201, 206-08 (1982), this 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

---

common law, *id.* at 180a (¶ VII(g)), and the court of appeals repeatedly invoked "*federal* common law" to recognize a right of action by Section 340B covered entities. *See, e.g.*, *id.* at 10a, 22a, 26a, 27a (emphasis added). The County also based its breach of contract claim on federal common law. *E.g.*, Appellants C.A. Br. 3, (Mar. 16, 2009); Appellants C.A. Br. 3, 14, 16 (Nov. 22, 2006).

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.

This Court explained that 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. The same principle here precludes 340B entities from using a pleading device to evade the absence of an implied right of action to enforce the 340B Act. *See 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").

This Court's decision in *Alexander v. Sandoval*, 532 U.S. 275 (2001), further establishes that even an affirmative intent by the Executive Branch to create substantive rights cannot trump the absence of an implied right of action. 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." *Id.* at 291. The Court explained that "[a]gencies may play the sorcerer's apprentice, but not the sorcerer himself." *Id.* That holding forecloses

any argument that the Secretary, by executing the PPA, could have conferred a private right of action.

B. The Court Of Appeals' Decision Violates The Court's Implied Right Of Action And Spending Clause Jurisprudence

1. The Ninth Circuit's recognition of a private right of action under the common law turns this Court's modern jurisprudence concerning such a right on its head. The premise of an implied right of action is that *Congress* intended to confer a private right of action but failed to say so expressly. *Thompson v. Thompson*, 484 U.S. 174, 179 (1988); *Cannon v. University of Chicago*, 441 U.S. 677, 688 (1979); *Cort v. Ash*, 422 U.S. 66 (1975). Absent congressional intent, "a cause of action does not exist and courts may not create one." *Sandoval*, 532 U.S. at 286-87. Thus, a court must always "first determine whether Congress *intended to create a federal right*." *Gonzaga Univ. v. Doe*, 536 U.S. 273, 283 (2002); *see Middlesex County Sewerage Auth. v. Nat'l Sea Clammers Ass'n*, 453 U.S. 1, 13 (1981) ("The key to the inquiry is the intent of the Legislature."); *California v. Sierra Club*, 451 U.S. 287, 293 (1981) ("[T]he ultimate issue is whether Congress intended to create a private right of action.").

Congress's exclusive authority to create new federal rights is rooted in the separation of powers: "In the absence of congressional intent, the Judiciary's recognition of an implied private right of action necessarily extends its authority to embrace a dispute Congress has not assigned it to resolve." *Stoneridge Inv. Partners, LLC v. Scientific-Atlanta, Inc.*, 552 U.S. 148, 164 (2008) (internal quotation marks omitted); *accord Gonzaga Univ.*, 536 U.S. at 285-86; *Northwest Airlines*, 451 U.S. at 94.

The Ninth Circuit's decision eviscerates the foundational underpinnings of those precedents. The court of appeals expressly assumed the absence of a private right of action by 340B entities under the statute, while simultaneously invoking federal common law to confer that right anyway. App., *infra*, 8a, 22a n.15, 29a. The Ninth Circuit reasoned that a private right of action furthered congressional intent because "[f]ederal common law contract remedies are one way of ensuring that drug companies comply with their obligations under the program and provide those discounts." *Id.* at 27a. It further asserted 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.* (quoting *Price v. Pierce*, 823 F.2d 1114, 1119-21 (7th Cir. 1987)). Far from furthering congressional intent, however, the decision patently subverts that intent by giving 340B entities a private right of action to enforce the very statutory requirements that Congress concededly did *not* intend to be enforced by private parties.

2. The Ninth Circuit's decision also flouts this Court's precedents under the Spending Clause. The Medicaid drug rebate and Section 340B ceiling price programs are Spending Clause enactments. As discussed, the Acts require drug manufacturers to enter into contracts under both the drug rebate and ceiling price programs as a condition of federal financial participation for outpatient drugs covered under State Medicaid plans. *Supra*, pp. 7-8; *see* Joint Explanatory Statement on H.R. 5193, 138 Cong. Rec. S17890 (1992) (explaining that 42 U.S.C. § 256b makes the "use of federal matching funds for payment for a covered outpatient drug [by State Medicaid programs] * * * contingent on * * * a manufacturer's entering into [ ] an agreement * * * under which the manufacturer agrees to provide rebates or discounts to" covered entities).

This Court has repeatedly made clear that intended beneficiaries of Spending Clause legislation may not sue to enforce statutory requirements that are a condition of federal funds unless there is an express or implied right of action under the statute. *See, e.g.*, *Sandoval*, 532 U.S. at 286; *Franklin v. Gwinnett County Pub. Sch.*, 503 U.S. 60 (1992); *Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1 (1981). Indeed, an implied right of action alone is insufficient. Because Spending Clause legislation "is much in the nature of a contract . . . if Congress intends to impose a condition on the grant of federal monies, it must do so unambiguously." *Pennhurst*, 451 U.S. at 17; *see, e.g.*, *Barnes v. Gorman*, 536 U.S. 181, 186 (2002); *Davis v. Monroe County Bd. of Educ.*, 526 U.S. 629, 640 (1999).

There is no implied right of action to enforce the drug pricing provisions under the 340B Act, and drug manufacturers accordingly had no warning that they could be subject to class action suits by private parties to enforce those provisions. Indeed, as the government explained in its amicus brief to the Ninth Circuit, the agency too "never imagined that a 340B entity could bring a third-party beneficiary lawsuit." Gov't Br., 2009 WL 4089524, at *12. In short, as the agency stated, permitting this challenge would "confer . . . rights never intended by the PPA signatories." *Id.* at *9. The court of appeals' decision casts aside decades of settled doctrine and paves the way for class action suits against drug manufacturers when neither the government nor the manufacturers could have possibly anticipated that result.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

LISA S. BLATT
Counsel of Record
JEFFREY L. HANDWERKER
ROBERT A. SCHWARTZ
ARNOLD & PORTER LLP
555 12th Street N.W.
Washington, DC 20004
(202) 942-5000
Lisa.Blatt@aporter.com

Counsel for Astra USA, Inc., AstraZeneca Pharmaceuticals LP and Zeneca Inc. and for All Petitioners for Purposes of this Petition

JAMES P. MUEHLBERGER
ALICIA J. DONAHUE
INA D. CHANG
SHOOK, HARDY & BACON LLP
333 Bush Street, Ste. 600
San Francisco, CA 94104
(415) 544-1900

Counsel for Aventis Pharmaceuticals Inc. and ZLB Behring LLC

RICHARD D. RASKIN
SCOTT D. STEIN
SIDLEY AUSTIN LLP
ONE S. DEARBORN ST.
Chicago, IL 60603
(312) 853-7000

Counsel for
Bayer Corporation

PAUL J. RIEHLE
MATTHEW A. FISCHER
SEDGWICK, DETERT,
MORAN & ARNOLD LLP
One Market Plaza
Steuart Tower, 8th Fl.
San Francisco, CA 94105
(415) 781-7900

Counsel for Bristol-Myers
Squibb Company

KIRKE M. HASSON
COLIN T. KEMP
PILLSBURY WINTHROP
SHAW PITTMAN LLP
50 Fremont Street
San Francisco, CA 94120
(415) 983-1000

Counsel for Merck & Co.,
Inc.

MOLLY M. LANE
MORGAN, LEWIS &
BOCKIUS LLP
One Market, Spear Street
Tower
San Francisco, CA 94105
(415) 442-1000

Counsel for Pfizer Inc.

FREDERICK G. HEROLD
DECHERT LLP
2440 West El Camino Real,
Suite 700
Mountain View, CA 94040
(650) 813-4800

*Counsel for Smithkline
Beecham Corporation d/b/a
GlaxoSmithKline*

PETER N. LARSON
JONES DAY
555 California St., 26th Fl.
San Francisco, CA 94104
(415) 626-3939

Counsel for Defendant-
TAP Pharmaceutical
Products Inc., Now Known
As Takeda
Pharmaceuticals North
America, Inc.

FLETCHER C. ALFORD
RYAN B. POLK
GORDON & REES LLP
275 Battery St., Ste. 2000
San Francisco, CA 94111
(415) 986-5900
Counsel for Wyeth, Inc.
and Wyeth
Pharmaceuticals, Inc.

APRIL 20, 2010

Blank Page