No. 09-1273

IN THE

JUN 21 2010

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.

THE COUNTY OF SANTA CLARA, On Behalf of Itself and All Others Similarly Situated,
Respondent.

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

BRIEF IN OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

MIGUEL MÁRQUEZ
County Counsel
TAMARA LANGE
Lead Deputy County Counsel
OFFICE OF THE COUNTY COUNSEL
SANTA CLARA COUNTY
70 West Hedding, East Wing
9th Floor
San Jose, CA 95110
(408) 299-5906

SANFORD SVETCOV
Counsel of Record
JEFFREY W. LAWRENCE
SUSAN K. ALEXANDER
AELISH M. BAIG
PHILLIP G. FREEMON
ROBBINS GELLER RUDMAN & DOWD LLP
100 Pine Street
26th Floor
San Francisco, CA 94111
(415) 288-4545
sandys@rgrdlaw.com

Counsel for Respondent

WILSON-EPES PRINTING CO., INC. – (202) 789-0096 – WASHINGTON, D. C. 20001

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QUESTION PRESENTED

The question framed by the petition does not accurately characterize respondent's cause of action or the Court of Appeals' decision. As the Court of Appeals held, this action is subject to federal contract law which, consistent with this Court's precedents, allows respondent to bring a third-party claim for breach of a government contract that is explicitly "'intended for his direct benefit.'" *Robins Dry Dock & Repair Co. v. Flint*, 275 U.S. 303, 307 (1927); *County of Santa Clara v. Astra, USA, Inc.*, 588 F.3d 1237, 1243-45 (9th Cir. 2009). Indeed, the Court of Appeals assumed that §340B, "[42 U.S.C.] §256b does not create a private cause of action." *Id.* at 1249 n.15.

This Court has emphasized that "private parties in appropriate cases may sue in federal court to enforce contractual rights created by federal statutes," a principle which is discrete from and "does not fit comfortably in [the] mold" of implied private right of action cases. *Jackson Transit Auth. v. Local Div. 1285, Amalgamated Transit Union, AFL-CIO-CLC*, 457 U.S. 15, 20, 22 (1982). Accordingly, the question presented is:

Whether the Court of Appeals correctly concluded that §340B does not displace a claim for breach of the contract it mandates between the federal government and petitioning drug manufacturers and that, under the federal common law of contracts, the "covered entities" who are the intended direct beneficiaries of that contract may sue petitioners for breach of their contractual obligations to cap the prices at which they sell drugs to covered entities?

PARTIES

Respondents are the County of Santa Clara, California, on behalf of its §340B (42 U.S.C. §256b) "covered entities," including a public hospital and associated clinics that the County funds, and the County of Santa Cruz, California, individually, and as representatives of all other similarly situated, covered-entity medical facilities, who allege they were overcharged for drugs in breach of the ten petitioning drug manufacturers' pharmaceutical pricing agreements with the government.

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INTRODUCTION

Petitioners, ten drug manufacturers ("Drugmakers"), attempt to create a conflict among the circuits by conflating a body of law that delineates the circumstances in which courts may recognize an implied private right of action under statute, with the distinct body of decisions consistently establishing that an intended third-party beneficiary of a government con-

tract may sue *on the contract* to enforce obligations for its direct benefit. This case addresses who is entitled to enforce a claim for breach of contract resulting from overcharges in violation of the petitioning drug manufacturers' agreement to cap the prices they charge to the covered entities that make up a critical part of the nation's healthcare safety net. There is no need to resort to implied right of action doctrine. Contrary to the petition, this case does not involve a free-standing federal common law claim. (Petition ("Pet.") 2-4) Rather, this Court's decisions plainly authorize respondent's suit to enforce the contract obligation that Congress mandated by statute for respondent's direct benefit.

The Second Amended Complaint ("Complaint") alleges, based on a series of reports from the Office of Inspector General of the Department of Health and Human Services ("OIG"), that, in breach of the contract created by §340B (42 U.S.C. §256b), Drug-makers have overcharged 97% of covered entities like respondent for drugs since 1999, and that such overcharging continues unchecked and is substantial. (ER 14-15¶¶4-7)[1] Several of the petitioning Drug-makers have pled guilty to violating Medicaid drug pricing requirements – but §340B has not been similarly enforced. (ER 418-20) AstraZeneca entered a plea of guilty in 2003 for violating various other drug pricing requirements and agreed to pay a $355 million fine. (ER 34¶67) Pfizer paid $9 million in 2002 to settle violations of a Medicaid rebate program. (ER 34¶68) In 2001, TAP Pharmaceutical Products paid $875 million in fines – $559.5 million for violating

[1] All references to "ER" and "SER" refer to the Excerpts of Record and Supplemental Excerpts of Record filed in the second appeal in this case, Ninth Cir. 09-15216.

Medicaid best pricing requirements similar to those in §340B. (ER 34¶69) Petitioners did not petition this Court until the lower courts' rulings made clear that they would have to produce documents revealing how they calculated drug pricing in violation of the 340B contract.

The fact that the federal law of contracts – like the Restatement and the law of many states – provides that an intended direct third-party beneficiary may enforce a breach of contract does not mean that "general federal common law" is being invoked to create a cause of action out of whole cloth. In this case, the Court of Appeals assumed without deciding that §340B does not by implication authorize a private right of action. Petitioners contend that in the absence of an implied statutory remedy, there can be no right to enforce their contractual obligations to the government. They do not dispute their obligations under the contracts, nor do they dispute here that respondents are intended direct third-party beneficiaries of the contract. Instead, petitioners assert that applying basic principles of contract law is somehow inconsistent with this Court's prescribed limitations on implied rights of action under statute.

Contrary to the petition, respondent, the County of Santa Clara ("Santa Clara" or "County") need not depend on an implied private right of action under §340B. Instead, the County sued for breach of the contract created by §340B. The Court of Appeals held that the County has the right to sue for breach of the government contract created by §340B – the pharmaceutical pricing agreement ("PPA" or "Contract") – a contract expressly intended for the direct benefit of the County's "covered entity" medical facilities. As the Court of Appeals concluded: "[W]e

are unable to discern any substantial purpose of the PPA *other* than to grant eligible covered entities a discount on covered drugs." *County of Santa Clara v. Astra, U.S.A., Inc.*, 588 F.3d 1237, 1246 (9th Cir. 2009) ("*Santa Clara II*") (emphasis in original). There is nothing novel in this holding.

This Court has long held that "private parties may sue in federal court to enforce contractual rights created by federal statutes" that "lacked express provisions creating federal causes of action." *Jackson Transit Auth. v. Local Div. 1285, Amalgamated Transit Union, AFL-CIO-CLC*, 457 U.S. 15, 22 (1982). This Court has already concluded that a suit to enforce a government contract is different from and "does not fit comfortably in [the] mold" of a statutory implied private right of action. *Id.* at 22, 29-30. Similarly, here the "gist of the [County's] position is not that the [statute] creates an implied right of action to sue for violation of the statute." *Id.* at 21. Instead, the County seeks to vindicate the rights of its covered entities under contracts intended for their direct benefit that were created by a federal statute which expressly provides them no remedy other than enforcement of the contract itself.

Consistent with this Court's longstanding contract law jurisprudence, respondents sued the Drugmakers as third-party beneficiaries of the government contract because it "'was intended for [their] direct benefit.'" *Robins Dry Dock & Repair Co. v. Flint*, 275 U.S. 303, 307 (1927); *German Alliance Ins. Co. v. Home Water Supply Co.*, 226 U.S. 220, 230 (1912); *Boyle v. United Techs. Corp.*, 487 U.S. 500, 505 (1988) (recognizing "liability to third persons" that "arises out of performance of the [government] contract" as a "'uniquely federal' interest").

The asserted conflict among the circuits does not exist. Petitioners' purported conflict mistakenly conflates cases involving statutory displacement of contract claims (which they wrongly characterize as implied right of action cases) from three circuits with third-party beneficiary contract cases in five other circuits. In all of these cases, the courts held that plaintiff could not sue, either because there was no implied right of action under statutes which provided administrative remedies (three circuits), or because the plaintiff was merely an incidental beneficiary of the contract (five circuits). Here, petitioners do not dispute the Court of Appeals' decision that respondent is the *intended direct beneficiary* of the contract, and the statute creating the contract provided *no administrative remedy*.

Petitioners' assertion that there is no general federal common law does not negate the Court of Appeals' holding that respondents are entitled to sue on a contract as intended direct third-party beneficiaries. This Court has long recognized that government contracts created by statute and involving "uniquely federal interests" can be enforced in federal court. *Clearfield Trust Co. v. United States*, 318 U.S. 363, 366-67 (1943); *United States v. Little Lake Misere Land Co.*, 412 U.S. 580, 592-94 (1973); *United States v. Kimbell Foods, Inc.*, 440 U.S. 715, 726-29 (1979). Whether the court applies federal common law as the contract provides, or state contract law, the choice of law does not affect the right to sue to enforce the contract. Indeed, while petitioners' *amici* simply rehash the petition's contentions, the Chamber of Commerce candidly concedes that this Court recognizes an exception to *Erie* for suits enforcing federal contracts. (*See Amicus* Brief at 8)

In sum, certiorari should be denied here because the question raised by Drugmakers' petition is not presented here. This is not an implied statutory private right of action case; this is a breach of federal contract case. There is no circumvention of implied right of action jurisprudence. The asserted circuit split does not exist.

STATEMENT OF THE CASE

Section 340B created a contractual mechanism requiring drug manufacturers that benefit from participating in Medicaid to sell drugs at discounted prices to "covered entities" that treat indigent Medicaid patients. 42 U.S.C. §256b(a)(1); *Univ. Med. Ctr. v. Shalala*, 173 F.3d 438, 439 (D.C. Cir. 1999). As the government's *amicus* brief in the Court of Appeals explained ("U.S. Br."), §340B was enacted in 1992 when "Congress became concerned that [drug] manufacturers were overcharging safety-net providers such as public hospitals, community health clinics, and similar [now-covered] entities." (U.S. Br. at 7, published in 2009 WL 4089524 (U.S. Oct. 27, 2009))[2]

A. Section 340B Requires Drugmakers to Contract with the Secretary to Provide Drugs at Discount Prices to Covered Entities

Section 340B provides, in relevant part:

> The Secretary [of Health and Human Services] shall enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to

[2] The pagination to the U.S. Br. is to the printed Westlaw version.

> be paid (taking into account any rebate or discount, as provided by the Secretary) to the manufacturer . . . by a covered entity . . . does not exceed an amount equal to the average manufacturer price for the drug. . . reduced by [a] rebate percentage . . . .

42 U.S.C. §256b(a)(1). The contract provides that its terms "shall be construed in accordance with Federal common law, and ambiguities shall be interpreted in the manner which best effectuates the statutory scheme." (ER 58(g)) On behalf of the Secretary, the §340B program is monitored by the Health Resources and Services Administration ("HRSA") within HHS. (ER 24¶34)

The plain language of the Contract expresses the clear intent of the contracting parties that Drugmakers charge "covered entities" like Santa Clara's medical facilities – no more than a discount or "ceiling" price for covered drugs as prescribed by the statute:

> Pursuant to requirements under section 340B of the Act, the Manufacturer agrees to the following:
>
> (a) . . . to charge covered entities a price for each unit of the drug that does not exceed an amount equal to the AMP [Average Manufacturer Price] for the covered outpatient drug reported . . . to the Secretary in accordance with the Manufacturer's responsibilities under section 1927(b)(3) . . . reduced by the rebate percentage.

(ER 53) The petitioning Drugmakers – which enjoy annual sales ranging from $5.8 billion to $16.5 billion (ER 18-23¶¶15-29) – entered into a §340B Contract with Santa Clara (ER 40¶¶102-103), and agreed to

sell drugs to the County's covered entities at discount prices as a condition of participating in and being paid by Medicaid. (ER 25¶38) The standardized Contract between the Secretary and the Drugmakers is attached to the Complaint. (ER 49-59)

Apart from the Contract itself which allows "such other remedies as may be available by law" (ER 56), §340B provides no remedies to covered entities to recover for being overcharged by Drugmakers. The statute does, however, provide that "The Secretary shall establish a mechanism to ensure that covered entities comply" with a provision prohibiting duplicate discounts. 42 U.S.C. §256b(a)(5)(A)(ii). The Secretary established such a mechanism allowing drug manufacturers to access the agency's elective dispute resolution process to recover from covered entities for any duplicate discounts made. (ER 55) But the Secretary's regulations expressly provide that no "covered entity is required to avail itself of this [agency dispute resolution] process before resorting to other available remedies." Manufacturer Audit Guidelines – Dispute Resolution Process 0905-2A-19, 61 Fed. Reg. 65406, 65411 (Dec. 12, 1996).

B. Under the Contracts Created by §340B, Covered Entities Are Entitled to Drugs at a Ceiling Price Computed from the Correctly Reported Average Manufacturer Price and Best Price

As the district court observed, under the Contract, the §340B ceiling price per unit is calculated by the following simple formula: "AMP [minus] Unit Rebate Amount ["URA"] = Ceiling Price[.] 42 U.S.C. 256b (a)(1)-(2)." (ER 5) In turn, the URA formula is the

"greater" of AMP minus BP, or 15.1% of AMP, as spelled out by the district court:

> The average manufacturer's price ("AMP") is (simplifying slightly) just the average price paid to the manufacturers by wholesalers in the United States. 42 U.S.C. 1396r-8(b)(3)(A), (k)(1). The unit rebate amount ("URA") is, in some circumstances, just a fixed percentage of the AMP, and in others is the AMP minus the 'best price,' term defined as (again simplifying slightly) the manufacturers' best price charged to wholesalers, with certain exclusions. 42 U.S.C. 1396r-8(c). Both the AMP and the 'best price' are calculated or collected *by the manufacturers* and are then simply *reported to* the Secretary. *Id.* at §1396r-8(b)(3)(A).

(ER 5-6)[3] As defined in the Contract, the AMP is an "average" unit price for each drug sold. (ER 51, 406-07) The data underlying that reported number includes all of the unit prices each manufacturer charged to its wholesalers for a specific drug during the previous quarter. They must retain a record of prices underlying AMP and "best price" data for ten years. 42 C.F.R. §447.510.

By contrast, "best price" ("BP") is simply the "lowest price available from the manufacturer" that the manufacturer charged to any of its customers during the prior quarter and requires no calculation. 42 U.S.C. §1396r-8(c)(1)(C)(i). Thus, to determine the correct ceiling price, Santa Clara must assess all of the manufacturer prices for a given drug both to

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[3] Citations and footnotes are omitted and emphasis is added unless otherwise noted.

determine the average and to determine which is the "lowest" or "best" price. To put it mathematically, Ceiling Price = AMP – (AMP – BP) = BP. In other words, the ceiling price is typically the best price.

C. When the Correct Best Price Is Lower than the Reported Best Price, the §340B Ceiling Price Decreases and Medicaid Rebates Increase – a Win-Win Result for Both States and Covered Entities

The OIG reports in the record reveal that typically it is the manufacturers' overstatement of BP that causes both lower Medicaid rebates to the States and overcharges to covered entities in excess of the correct ceiling price for drugs purchased under the §340B program. (ER 14-15¶4; ER 64-67) Indeed, Drugmakers unwittingly conceded in their Court of Appeals brief ("DB") that BP is the component of the formula where they try to evade use of "a single low price transaction" that "could create a significant rebate liability to Medicaid." (DB 16)[4]

It is also evident that when actual BPs are lower than the BPs inaccurately *reported* by the manufacturers, as alleged, the results would benefit both covered entities in the form of lower ceiling prices and the States in the form of higher Medicaid rebate amounts. Thus, both the Medicaid and 340B programs

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[4] Reported cases likewise reveal the manufacturers' efforts to evade BP requirements. *E.g.*, *Steinke v. Merck & Co.*, 432 F. Supp. 2d 1082, 1086-87 (D. Nev. 2006) (Upholding complaint challenging manufacturer's calculation of BP); *Mass. v. Mylan Labs.*, 357 F. Supp. 2d 314, 329 (D. Mass. 2005) (held state can sue as intended third-party beneficiary of Medicaid rebate agreement any "'manufacturer that failed to calculate its best price obligations in accordance with the Rebate Agreement or CMS guidance'").

benefit from correct lower BP submissions. Both programs gain from accurate data; there are no antagonistic results as petitioners claim. (Pet. 25-26)

Further, contrary to petitioners' assertion (*Id.* 25), covered entities do not benefit when the correct AMP is lower than the AMP reported. The URA under Medicaid would be lower when the correct AMP is lower than that reported, but as the district court in this case recognized:

> If defendants have *not* committed significant reporting errors, there should be no widespread impact on the Medicaid rebate program, and if defendants *have* systematically misreported data to the Medicaid program, defendants fail to explain why it would be undesirable (for anyone other than defendants) for such conduct to come to light.

(ER 9, emphasis in original) As the government's *amicus* brief in the Court of Appeals acknowledged, drug manufacturers cannot comply with the contract using just any pricing data they reported. They must use "accurately reported AMP and best price" data. (U.S. Br. at 10-11)

D. As Inspector General Reports Reveal, Drugmakers Have Consistently Overcharged 97% of Covered Entities Millions of Dollars Since 1999 in Breach of Their Agreement to Cap Drugs at Discount Prices

In combination, covered entities spent $3.4 billion on drugs in 2003. (ER 14¶2) Santa Clara §340B medical facilities spent $29 million in 2003, $30 million in 2004, and $31 million for the first eight months of 2005. (ER 14¶3)

The Complaint alleges, based on a series of reports from the OIG, that, in breach of the §340B Contract, Drugmakers have overcharged 97% of covered entities like respondent for drugs since 1999, that such overcharging continues unchecked, and that it is substantial. (ER 14-15¶¶4-7) A 2003 OIG report revealed there were $6.1 million in overcharges in 1999 by five manufacturers for just 11 drugs surveyed. (ER 14-15¶4; 67; 420; 430 n.17) The overcharges occurred because drug manufacturers incorrectly excluded certain low-price sales "from their best price determinations, thereby increasing the prices charged to 340B entities." (ER 64-67) In 2004, HRSA asked the five manufacturers to refund the $6.1 million in §340B overcharges for 1999; a year later no refunds had been issued. (ER 14-15¶4; 420; 430 n.17) As noted above, several Drugmakers have paid hundreds of millions in fines to Medicaid – but §340B has not been similarly enforced. (ER 34, 418-20)

A June 2004 OIG report found that in one month, September 2002, there were $41.1 million in overcharges. (*Id.*) Thus, extrapolating for the entire year, the OIG estimated there were nearly $500 million in overcharges in 2002. (*Id.*) Although the June 2004 OIG report was withdrawn in October 2004 to correct the data concerning overcharges, the withdrawal reaffirmed that the pricing problems found still exist:

> "Despite our withdrawal of the Report because of problems with the underlying data, we continue to believe there are systemic issues that lead to price discrepancies within the 340B Drug Pricing Program. These newly-discovered data problems do not affect the validity of three findings of the Report."

(ER 32-33¶63) The three findings reaffirmed by the OIG, and embodied in the Complaint, are: (i) there is weak or non-existent agency oversight of drug pricing and no process "to confirm that §340B entities receive the ceiling price"; (ii) covered entities have no means to "verify" whether they are being charged the correct price due to manufacturers' assertion of "confidentiality" under the statute; and (iii) drug "manufacturers' 340B ceiling price calculations" are neither reported to nor "verified" by HHS. (*Id.*)

E. The Secretary Has Not Enforced §340B Contracts

As summarized in the Complaint (ER 28-30), an October 2005 OIG report also concluded that the agency "does not have the necessary legislative, regulatory, or contractual authority to effectively oversee the 340B Program." (ER 419) In a May 2006 OIG report auditing AMP determinations, significant errors were found in §340B price calculations:

> In our review of the 340B program, we found two primary issues that have implications for the use of AMP as the basis of Medicaid reimbursement: the timely submission of AMP data by manufacturers and the accuracy of reported AMP data.

(ER 456) The Complaint further alleges that covered entities cannot verify the prices they are charged because Drugmakers refuse to disclose their pricing data, knowing the government cannot "impose consequences for violation[s]." (ER 28-30¶¶47-53) The OIG's 2005 investigation confirmed this allegation. (ER 418-420)

The OIG noted that §340B allows the Secretary to terminate manufacturers from the Medicaid and

§340B programs, but that such a severe sanction would be counter-productive because it would reduce "access to medications for millions of Medicaid and 340B beneficiaries." (ER 419) The OIG also found that the agency "does not verify the official Government 340B ceiling prices against manufacturers' 340B ceiling prices [charged to covered entities] to detect discrepancies. Manufacturers must calculate their ceiling prices to participate in the 340B program, but they are not required to report their final ceiling prices to [the agency]." (ER 418) The OIG stated:

> [The agency] does not check and thus is unable to detect whether manufacturers perform the calculation properly and whether entities are paying at the correct ceiling price.

(ER 419)

In a September 1, 2005 Senate Finance Committee letter to the Secretary, Senator Grassley expressed concern over OIG's findings that the agency had no access to Drugmakers' pricing data to even attempt to ensure compliance. (ER 172) Senator Grassley concluded there were "systemic problems" in the §340B program that the Secretary should address. (ER 173)

Although the Contract provides for an elective administrative "dispute resolution process" to require a manufacturer to reimburse covered entities "for discounts withheld" (ER 55), the process the Secretary has never initiated that process, and does not have the resources to do so. (ER 28-29¶¶50-52; 419; *see* ER 25¶35) Senator Grassley's letter states that: "According to the OIG, no Secretary has ever in-

itiated the dispute resolution process." (ER 173) Moreover, the Contract itself expressly provides that the elective dispute process does not preclude "exercising such other remedies as may be available by law." (ER 56(e)) The Secretary has unequivocally stated: "Covered entities . . . are not required to enter [its] informal process for resolution of disputes regarding section 340B," before "resorting to other remedies" available by law. 61 Fed. Reg. at 65411-12.

The government's *amicus* brief reveals why covered entities like respondents' have been forced to resort to suit against the Drugmakers. The government states that "if a [§]340B entity believes it is being overcharged, it can ask the manufacturer to participate in informal dispute resolution" – but it acknowledges "[n]o party is required to enter dispute resolution." (U.S. Br. at 8) The government admits that in a "not well-publicized" manner, the agency "sometimes fields calls from covered entities asking if they were overcharged for a specific drug," and "will give the entity a yes or no answer" but "[b]ecause of confidentiality" afforded the Drugmakers, "will not give the entity additional information." (*Id.*) Thus, the government's brief confirms the OIG finding of inadequate government capacity and authority to enforce §340B.

F. After the District Court Dismissed Respondent's Contract Claim, the Court of Appeals Reversed and Held that the County Could Sue the Drugmakers as Intended Direct Beneficiaries of the Contract

The County initially sued ten major Drugmakers in state court under state law for overcharging the County's "covered entity" public health facilities for

drugs. After Drugmakers removed the action to federal court (ER 635: Doc. 1),[5] the County filed the Complaint, alleging various claims, including a claim for breach of contract. (ER 12-48)

The Complaint alleges that many of Santa Clara's medical facilities are §340B covered entities that provide health care, including prescription and over-the-counter drugs, to indigent patients covered by Medicaid. (ER 13-18¶¶1-2, 10-13) Like all California counties, Santa Clara is required to provide health-care as a "'provider of last resort'" to residents who are not able to have their basic healthcare needs met elsewhere. Cal. Welf. & Inst. Code §17000. (ER 18¶13) In support of the contract claim, the Complaint alleges that the ten Drugmakers entered into contracts with the Secretary under which they each agreed to sell drugs to §340B covered entities at discount prices, and which they each breached by charging more than the ceiling price prescribed by the Contracts and mandated by the federal statute. (ER 23-26¶¶31-45; 40-41¶¶101-104)

The district court granted Drugmakers' motion to dismiss the Complaint, concluding that Santa Clara was not entitled to sue as a third-party beneficiary of the Drugmakers' contracts with the Secretary. (Docs. 196, 212) The district court reasoned that entities may sue for breach of a contract to which they are not a party if two criteria are met: "(1) the signatories intended [the entities] to benefit directly" and (2) "intended [the entities] to have the right to sue for performance." (Doc. 196:11) The court held that the first test was satisfied, ruling that the contract

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[5] "Doc." references are to Document numbers in the district court docket. No. C-05-03740-WHA (N.D. Cal.).

clearly identified "covered entities" like plaintiffs as the intended beneficiaries of its discount prices: "These provisions clearly benefited covered entities." (Doc. 196:12) The court added that the stated purpose of §340B – which commands the Secretary to enter into these contracts – suggests that "Congress intended to benefit [covered entities] directly." (Doc. 196:13) Despite ruling that plaintiffs were the intended direct beneficiaries of the contract, the court imposed a second requirement that there must be a "'clear intent'" found within the four corners of the contract giving third-parties the right to sue to enforce its provisions. (Doc. 196:11-12)

On Santa Clara's appeal from dismissal of its contract claim, the Court of Appeals reversed and held that Santa Clara's §340B "covered entities" were entitled to sue the Drugmakers as intended direct third-party beneficiaries of Drugmakers' PPA Contracts with the Secretary:

> Applying the federal common law of contracts, we hold that the covered entities are intended direct beneficiaries of these agreements and thus have the right to enforce the agreements' discount provisions against the Manufacturers and sue them for reimbursement of excess payments.

Santa Clara v. Astra, USA, Inc., 540 F.3d 1094, 1098 (9th Cir. 2008) ("*Santa Clara I*"). The Court of Appeals correctly held that the district court erred in imposing a second requirement that the contract contain a specific right to sue provision. The second requirement does not apply to intended direct beneficiaries of the contract, only to members of the public who are incidental beneficiaries. *Id.*, citing *Montana v. United States*, 124 F.3d 1269, 1273-74 (Fed. Cir.

1997); *Klamath Water Users Protective Ass'n v. Patterson*, 204 F.3d 1206, 1210-12 (9th Cir. 1999). Petitioners did not seek rehearing on this issue, and the petition for certiorari does not challenge this holding.

The Court of Appeals also held that "allowing such suits under the [Contract] is consistent with Congress' intent in enacting the Section 340B program," and rejected Drugmakers' contention that permitting a contract claim created an implied private right of action under the statute. *Santa Clara I*, 540 F.3d at 1100, 1103. The Court of Appeals distinguished the cases cited by Drugmakers because in those cases the statute created an administrative remedy, thereby negating any intent to provide a private remedy. *Id.* at 1106-08.

The Court of Appeals also expressly rejected the Drugmakers' contention that their "pricing data" – used in calculating §340B ceiling prices under the contract – was confidential and could not be disclosed. *Id.* at 1099, 1105-06. The Court of Appeals reasoned that court-ordered discovery fit within the "otherwise required by law" exception to confidentiality explicitly provided for in the Contract. (ER 56 v(a)) Finally, the Court of Appeals rejected Drugmakers' assertion of primary jurisdiction as an independent ground for affirmance. The Court found that because Santa Clara's contract claim was not particularly complicated and did not challenge the agency's guidance for calculating prices under 42 U.S.C. §1396r-8, there was no need to defer to the agency. *Santa Clara I*, 540 F.3d at 1109.

Although the scope of the Contract was neither at issue nor briefed by the parties (ER 378-90; 392-94),

the Court of Appeals severely limited its effect in its 2008 decision, stating:

> The PPA [Pharmaceutical Pricing Agreement] is drafted, for instance, so that covered entities are entitled only to the average manufacturer price ["AMP"] *reported* to the Secretary; they cannot claim that the reported figure was itself somehow erroneous.

Santa Clara I, 540 F.3d at 1109 (emphasis in original). Neither party petitioned for rehearing.

Immediately after remand, and relying on the single sentence in the Court of Appeals' decision appearing to limit the evidence of breach of contract to the price "reported," Drugmakers moved for a protective order to preclude discovery by Santa Clara as to any data "underlying the calculation of Average Manufacturer Prices" and expanded this to "best-price" data. (ER 5, 15, 262-63) The district court reluctantly granted Drugmakers' motion for protective order, stating that but for the sentence in the Court of Appeals' decision, it "would be inclined" to rule for the plaintiff to allow discovery to enable Santa Clara to challenge the price calculated. (ER 7)

The district court certified (ER 10-11) and the Court of Appeals accepted an interlocutory appeal under 28 U.S.C. §1292(b). (Doc. 310) After full briefing by the parties, the Court of Appeals requested an *amicus* brief from the government on the issue of primary jurisdiction. The petition fails to mention that in its *amicus* brief, the government agreed with respondents that the Drugmakers are not free to calculate ceiling prices using "reported AMP and Best Price data" but must use and report "accurate [pricing] data." (U.S. Br. at 9-11 & n.11)

The government also acknowledged that the Court of Appeals "should refrain from invoking primary jurisdiction now." (*Id.* at 12-13) The government explained that "if any overcharging resulted from purely mechanical errors, or certain obvious and intentional fraud, the issues would not be sufficiently complex to require referral to HHS." (*Id.*) Thus, the government agreed that if discovery revealed obvious and intentional overcharges, as the County alleged, the statutory scheme and the Secretary's enforcement authority would not be implicated, and "primary jurisdiction need not be invoked" because "[n]o special agency expertise is implicated by such straightforward claims." (*Id.* at 13)

The Court of Appeals accepted the government's submission and did not invoke the agency's primary jurisdiction. *Santa Clara II*, 588 F.3d at 1250 & n.19. The Court of Appeals vacated its initial decision and reissued it allowing the County to sue on the Contract without the sentence limiting suit to prices *reported*. *Id.* at 1252.

REASONS FOR DENYING PETITION

This petition arises from the Court of Appeals' reissuance of a 2008 decision in which the panel previously had held that respondents, as intended direct third-party beneficiaries of the contract, can enforce the petitioning manufacturers' contractual obligation not to charge 340B entities more than the ceiling price for each drug. The decision from which petitioners now seek certiorari was modified only to clarify that the contractual obligation itself is not limited, as the manufacturers had argued, to charging 340B entities the ceiling prices manufacturers *actually reported* to the government. Rather, as the

government's *amicus* brief to the Court of Appeals explained, "manufacturers must *compute* ceiling prices *using* only *accurately reported values*." (U.S. Br. at 11)

The effect of the new panel decision, after the district court certified an appeal from a protective order, is to permit Santa Clara to obtain discovery of the manufacturers' actual pricing conduct. Notably, petitioners only elected to seek certiorari after the Ninth Circuit reissued its opinion.

Petitioners' legal theory erroneously conflates distinct bodies of law to create the appearance of a conflict in the lower courts. Likewise, their assertion of burden provides no valid basis for certiorari; it merely reflects petitioners' attempt to avoid exposure to liability for overcharging safety net healthcare providers.

I. THE ASSERTED CONFLICT AMONG THE CIRCUITS DOES NOT EXIST

As the district court and Court of Appeals proceedings make clear, respondent seeks recovery for breach of contract. (2006 ER 45-49)[6] There is no split of authority on the basic contract principles involved in resolving third-party rights – nor do petitioners assert any such split.

The Court of Appeals' analysis is based entirely on "general principles for interpreting contracts," and grounded in application of the rule concerning third-party beneficiary rights in the Restatement (Second) of Contracts. *Santa Clara II*, 588 F.3d at 1244-45

[6] All references to "2006 ER" and "2006 SER" refer to the Excerpts of Record and Supplemental Excerpts of Record filed in the first appeal in this case, Ninth Cir. 06-16471.

("'[A] third party who is an intended beneficiary of a contract may sue to enforce the contract or to obtain an appropriate remedy for breach.'"). That approach follows longstanding precedent from this Court, which has drawn on basic contract principals to resolve questions of third-party rights. *Robins Dry Dock*, 275 U.S. at 308-09.

In an attempt to recharacterize plaintiffs' claim, Drugmakers now seek to resurrect a strawman-theory that any challenge under the contract is effectively a challenge under the statute itself and somehow an impermissible attempt to establish a private right of action under the statute. (Pet. 2-3) Petitioners' attempted recharacterization mistakenly conflates implied statutory rights of action with respondents' suit for breach of the contract between Drugmakers and the Secretary for respondents' direct benefit. These are discrete claims. *Jackson Transit*, 457 U.S. at 22, 30. Under Federal Rules of Civil Procedure 12(b)(6), the claim alleged must be construed in plaintiffs' favor; Drugmakers are not free to recharacterize it. *Swierkiewicz v. Sorema, N.A.*, 534 U.S. 506, 512-14 (2002). Indeed, the district court recognized that plaintiffs advanced a federal common law contract claim, and did not address Drugmakers' implied statutory right-of-action theory. (2006 ER 45-49)[7]

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[7] Moreover, petitioners' contention that the contract claim must be viewed as an implied statutory private right claim was belated even at its inception. Drugmakers did not raise this theory in their motion to dismiss, but only for the first time in their district court reply and then only in a perfunctory one-line parenthetical to a case citation in support of their main contention that the contract contained no specific intent-to-sue. (2006 SER 118-19, 127-28) Because it was raised in reply, plaintiffs had no chance to address it in their papers (2006 SER

Petitioners rely on cases from the Second, Sixth and Tenth Circuits in an attempt to construct a circuit split. But the asserted conflict does not exist. As discussed below, the Second, Sixth and Tenth Circuit cases cited by Drugmakers simply applied settled law to preclude private suits because the relevant *statute provided a mandatory administrative remedy*. Here, §340B establishes no remedy to covered entities apart from the contract itself. There is no circuit conflict on this principle – just different results for different types of statutes. Indeed, as discussed below, none of the five circuit cases petitioners cite for the supposed contrary view were implied private statutory actions; instead they turned on determinations that plaintiffs were *incidental* third-party beneficiaries, rather than intended, direct beneficiaries of the contract, as respondents undisputedly are here.

A. Petitioners Mistakenly Conflate Asserted Implied Statutory Private Right of Action Cases with the Contract Claim in This Case

Petitioners' purported implied right of action cases are inapposite and create no conflict. Each of them turns on the existence of a statute-mandated administrative remedy. No such remedy is provided by §340B.

122-24), and the district court did not address it either. (2006 ER 45-48) The Court of Appeals nevertheless rejected the contention on the merits when Drugmakers raised it as an alternative ground on appeal. *Santa Clara II*, 588 F.3d at 1249-51. But the Court of Appeals' principal holding was that, as intended direct third-party beneficiaries, respondents were entitled to sue under the Contract. *Id.* at 1243-49.

In the Second Circuit case cited by petitioners, a federal statute provided that prevailing wages under city construction contracts would be "'predetermined by the Secretary of Labor,'" and provided an administrative remedy for violations. *Grochowski v. Phoenix Constr.*, 318 F.3d 80, 83 (2d Cir. 2003). Based on those provisions, the Second Circuit held that it would be "'inconsistent with'" and "'would interfere with the implementation of'" the statute, the Davis-Bacon Act, to allow a private state contract suit. *Id.* at 85-86 (concluding "plaintiff's state-law claims are indirect attempts at privately enforcing the prevailing wage schedule contained in the [statute]"). *Grochowski* is clearly inapposite. It is premised on the "'elemental canon' of statutory construction that where a statute expressly provides an exclusive remedy, 'courts must be especially reluctant to provide additional remedies.'" *Id.* at 85, quoting *Karahalios v. Nat'l Fed'n of Fed. Employees, Local 1263*, 489 U.S. 527, 533 (1989). Here, §256b does not "expressly provide" any remedies to covered entities. Unlike the Davis-Bacon Act, §256b is silent about the agency's power to promulgate regulations against manufacturers with the force of law. Unlike *Grochowski*, the private action here is consistent with the statutory scheme which created the contract. The statute provides no other remedy that would preclude suit on the contract. The Court of Appeals correctly so ruled. *Santa Clara II*, 588 F.3d at 1249-51.

Similarly, the Sixth Circuit case petitioners cite involved a discharged employee who claimed he was a handicapped individual entitled to bring a cause of action under the Vocational Rehabilitation Act. *Hoopes v. Equifax, Inc.*, 611 F.2d 134 (6th Cir. 1979). The court's entire analysis appeared in a single sen-

tence which highlights the difference here: "Even if appellant is a handicapped person under the Vocational Rehabilitation Act of 1973, 29 U.S.C. §793, *that statute provides for an administrative remedy* through the Department of Labor and does not authorize a private cause of action in the courts." *Hoopes*, 611 F.2d at 135.

Likewise, in the Tenth Circuit case, arising under the same statute, 29 U.S.C. §793, the Court of Appeals declined to allow a contract claim precisely because "the comprehensive remedial scheme provided in the statute dictates against implying another remedy" for breach of any government contract employing handicapped individuals. *Hodges v. Atchison, T & S.F.R. Co.*, 728 F.2d 414, 416 (10th Cir. 1984). In stark contrast, there is no mandatory administrative remedy for "covered entities" in this case.

The crucial omission in petitioners' analysis of their asserted circuit split is that this case involves a contract for the *direct benefit* of respondents and *no remedial scheme*, while petitioners' cases each involved statutes that created another express administrative remedy. *Hoopes*, 611 F.2d at 135 (the statute "provides for an administrative remedy through that Department of Labor"); *Hodges*, 728 F.2d at 415-16 (statutes provided for an administrative remedy or arbitration – not a private action); *Grochowski*, 318 F.3d at 85 (the statute created a mandatory administrative remedy). Because a private breach of contract action was found inconsistent in each case with Congress' creation of an express alternative remedy, no contract claim was permitted. *See Santa Clara II*, 588 F.3d at 1250-51 (analyzing *Grochowski* as a case involving statutory abrogation of state law claims).

Here, however the statute creates the contract for respondents' direct benefit and provides no alternative remedy. Instead, the PPA provides for an "elective dispute resolution process" that the Secretary has discretion to initiate (ER 55), but the contract explicitly states that the elective process does not "preclude" resort to "such other remedies as may be available by law." (ER 56) In interpreting §340B and the 340B Contract, the Secretary unambiguously stated that: "No manufacturer or covered entity is required to avail itself of this [agency dispute resolution] process before resorting to other available measures." 61 Fed. Reg. at 65411. Thus, as the agency itself interprets §340B, Congress did not intend to place jurisdiction over enforcement of §340B ceiling prices either preliminarily or exclusively within the agency. The agency's interpretation of the statute is entitled to deference. *Chevron, USA, Inc. v. NRDC*, 467 U.S. 837, 842 (1984). The 340B Contract expressly contemplates suits for breach of contract. The Court of Appeals correctly so held, and the petition does not contest that holding.

B. The Five Cases Petitioners Cite as Creating a Circuit Split Were Not Implied Statutory Actions, but Third-Party Contract Cases Involving Incidental, Not Intended Beneficiaries

Contrary to petitioners' description, none of the five decisions purportedly creating a conflict with the Second, Sixth or Tenth Circuits is an implied right of action case. Rather, they all involve alleged contract claims. In all five cases, the courts recognized that a third-party beneficiary could sue for breach of contract if it were an intended direct beneficiary, but

concluded the plaintiffs were only incidental beneficiaries, not intended direct beneficiaries.

In *Falzarano v. United States*, 607 F.2d 506 (1st Cir. 1979), the court held that plaintiffs were "merely incidental beneficiaries," not "intended beneficiaries," and that, under the statute, "[a]uthority is given to the Secretary to seek enforcement if necessary." *Id.* at 510-11. Likewise, in *Perry v. Hous. Auth. of Charleston*, 664 F.2d 1210 (4th Cir. 1981), the court held that tenant plaintiffs were "incidental beneficiaries" and not direct beneficiaries, and as such had no third-party right under contract between their landlord, the housing authority, and the federal agency. *Id.* at 1218. Similarly, in *Nguyen v. United States Catholic Conference*, 719 F.2d 52 (3d Cir. 1983), the court held that refugees "could not be considered third-party beneficiaries" of contracts between the Catholic church *and* the government. *Id.* at 56.

In *Dewakuku v. Martinez*, 271 F.3d 1031 (Fed. Cir. 2001), contrary to petitioner's assertion that the court "entertained a third-party beneficiary common law claim for breach of contract" (Pet. 16), the Federal Circuit found that because the contract expressly provided there were "no third party contract rights conferred," plaintiff was "not an intended third party beneficiary" who could enforce a contract between the government and the Indian public housing authority. *Id.* at 1040-42.

In *D'Amato v. Wisconsin Gas Co.*, 760 F.2d 1474 (7th Cir. 1985), the only case previously cited by petitioners, the court held that an employee of a government contractor was only an incidental beneficiary, not an intended "direct" beneficiary of the contract between his employer and the government, and also held the statutory grant of an exclusive

administrative remedy precluded a right of action. *Id.* at 1477-81. Here, the Ninth Circuit found, under the precise terms of the Contract that respondents were the intended direct beneficiaries of the Contract, and that §340B provided no remedy to respondents other than the Contract. *Id.*

In sum, the Court of Appeals' decision does not "deepen[] an existing 5-3 circuit" split. (Pet. 2, 12) There is no split – just two discrete lines of settled authority. Indeed, for the very obvious reason that there is no conflict, petitioners have never even mentioned the Sixth and Tenth Circuit cases they now cite in the petition during the entire five years of this litigation, and petitioners have never before cited the cases from four of the five other circuits that supposedly are in conflict.

C. Neither §340B Nor This Court's Implied Right of Action Jurisprudence Displaces Respondent Covered Entities' Right as Intended Direct Beneficiaries to Sue for Breach of Contract

Contrary to the petition, the County's contract claim is not displaced by the statute. Section 340B neither precludes a private right of action expressly, nor does so implicitly by creating other remedies. 42 U.S.C. §256b. The statute simply mandates a contract and establishes the principal obligation to be included in the contract – drug manufacturers must charge covered entities like respondent's medical facilities no more than a ceiling price according to the formula set forth in the statute. *Id.* Respondent sues to enforce the contract.

While the *contract* creates an administrative dispute resolution process, that process is explicitly

"elective" (ER 55, §IV(a)) and non-exclusive, allowing "such other remedies as may be available by law." (2006 ER 94) Apart from being optional, the administrative process is concededly ineffective and unused. The department does not have the resources or authority to provide a remedy or to provide effective oversight. (ER 418-20) As the Inspector General found, "no Secretary has ever initiated the dispute resolution process." (ER 173)

Despite years of criticism by the Inspector General, including reports finding millions of dollars in overcharges, and rebuke from Congress, the Secretary has not resolved the issues causing overcharges and lacks the resources to do so. As the Inspector General found: "HRSA does not have the necessary legislative, regulatory, or contractual authority to effectively oversee the 340B program" or to "enforce the consequences for violations as stated in HRSA's [Contract]." (ER 419-20)

None of the principal cases from this Court cited by petitioners as precluding an implied statutory private right of action involved a contract claim arising from a government contract created by statute to implement uniquely federal interests. *Alexander v. Sandoval*, 532 U.S. 275, 287 (2001) (disparate impact discrimination claim); *Virginia Bankshares v. Sandberg*, 501 U.S. 1083, 1102 (1991) (securities fraud claim); *Wheeldin v. Wheeler*, 373 U.S. 647, 651 (1963) (improper issuance of federal subpoena). Petitioners do not suggest otherwise. (Pet. 4, 29-30)

Petitioners cite *United States v. Erika, Inc.*, 456 U.S. 201 (1982), as their lone example of this Court's refusal to find an implied statutory private right of action involving a breach of contract. (Pet. 29-30) But the Medicare statute at issue in *Erika* is very

different from §340B and that difference supports the Court of Appeals' conclusion here that Congress did not intend to displace an intended direct beneficiary breach of contract claim to enforce the uniform contract created by §340B. The Medicare statute provided an elaborate multi-tiered agency review procedure, but omitted any procedure for judicial review of the insurance carrier's determination of health benefit claims under the statute. *Erika*, 456 U.S. at 202-06. The plaintiff in *Erika* filed suit against the government, not against the insurance carrier who refused payment, and sought recovery under the Social Security Act and applicable regulations. *Id.* at 205 & n.4. This Court found the administrative remedies provided by the statute, along with the absence of any provision for judicial review, demonstrated that Congress intended to foreclose judicial review of the agency's action by the Court of Claims under the Tucker Act. (28 U.S.C. §1491). *Id.* at 206-08.

In light of the statute-mandated administrative scheme in *Erika*, this Court also addressed plaintiff's alternative contract claim against the government, concluding that it too was precluded because the contract was subject to the statute's mandatory administrative review procedure and the statute's preclusion of judicial review. *Id.* at 211 n.14. There is no such administrative remedy or judicial preclusion in §340B. In fact, §340B only directs the Secretary to adopt procedures to ensure that covered entities comply with the program. 42 U.S.C. §256b(a)(5). And, both the §340B Contract (ER 56) and the Secretary's regulations explicitly state that "[c]overed entities . . . are not required to enter [the] informal process for resolution of disputes regarding section 340B" before "resorting to other remedies" available

by law. 61 Fed. Reg. at 65411-12. Thus, the reasoning of *Erika* supports appropriate third-party enforcement of federal contracts, irrespective of any separate implied statutory right of action.

Indeed, *Erika* confirms that there is no unresolved split in the circuits. Rather, to the extent the Second Circuit's decision in *Grochowski* conflicts with the decision below in this case, this Court's analysis in *Erika* demonstrates that the Second Circuit's reasoning was defective. It should have conducted the sort of preemption or displacement analysis modeled in *Erika*, called for by Judge Lynch in dissent in *Grochowski*, and conducted by the Court of Appeals in this case.

In sum, certiorari is unwarranted here because this is a contract claim – not an implied private statutory claim. Not only is there no conflict among the circuits, but as discussed next, petitioners do not even challenge the Court of Appeals' principal holding.

II. PETITIONERS DO NOT CHALLENGE THE COURT OF APPEALS' HOLDING THAT RESPONDENTS ARE INTENDED DIRECT THIRD-PARTY BENEFICIARIES OF THE PHARMACEUTICAL PRICING AGREEMENTS

Consistent with this Court's precedents and the Restatement, the Court of Appeals held that when the contract reflects the "express or implied" intent of the signatories to the contract to benefit third-parties directly, they have the right to sue as the *direct* "intended beneficiaries" of the contract. *Santa Clara II*, 588 F.3d at 1244-46; citing *Klamath*, 204 F.3d at 1210-11; Restatement (Second) of Contracts §304

(1981) ("A promise in a contract creates a duty in the promisor to any intended beneficiary to perform the promise, and the intended beneficiary may enforce the duty."); *see Robins Drydock*, 275 U.S. at 307 (same).

The Court of Appeals correctly rejected the district court's additional requirement that the contract contain a specific right to sue provision. Such a provision is required only when members of the public seek redress as *indirect* "incidental beneficiaries" – a situation not remotely present here. The petition does not contest this holding by the Court of Appeals, because Drugmakers know it is correct.

The notion of a two-part test for a third-party's rights to enforce a government contract appears to originate from the Claims Court decision in *Baudier Marin Elecs., Sales and Serv. Inc. v. United States*, 6 Cl. Ct. 246, 249 (1984). In subsequent cases, however, the Court of Federal Claims reconsidered the two-part test and concluded that there was no basis for the second requirement when the party seeking redress was the intended direct beneficiary of the contract. *Schuerman v. United States*, 30 Fed. Cl. 420, 428-33 (1994). *Schuerman* held the second requirement is superfluous when the third-party is an intended direct beneficiary. *Id.* at 432-33.

In *Montana*, 124 F.3d at 1273, the Federal Circuit agreed with *Schuerman* and specifically rejected the contention that the contract must contain an explicit right-to-sue provision in order for a third-party to enforce a government contract. *Montana*, 124 F.3d at 1273; *Glass v. United States*, 258 F.3d 1349, 1354 (Fed. Cir. 2001).

The Ninth Circuit subsequently followed *Montana* and held that intended direct beneficiaries could sue. *Klamath*, 204 F.3d at 1211. The petition does not dispute that the Court of Appeals panel in this case correctly applied *Montana* and *Klamath*, consistent with this Court's decisions in *German Alliance*, 226 U.S. at 230 and *Robins Drydock*, 275 U.S. at 307. *Santa Clara II*, 588 F.3d at 1244-46.

III. THE COURT OF APPEALS ACCEPTED THE GOVERNMENT'S SUBMISSION THAT THE COUNTY'S SUIT CAN PROCEED WITHOUT DISRUPTING GOVERNMENT PROGRAMS OR INVOKING PRIMARY JURISDICTION

Although petitioners do not purport to challenge the lower court ruling on primary jurisdiction, their contention that allowing the case to proceed will burden them unfairly is an attempt to take another bite of that same apple. In its *amicus* brief, the government urged the Court of Appeals to "refrain from invoking [the Secretary's] primary jurisdiction now." (U.S. Br. at 9, 12-13) The government explained that "plaintiff's suit does not require" agency involvement if discovery reveals that the "overcharging" by Drugmakers in breach of the pharmaceutical pricing agreements "resulted from purely mechanical errors, or certain obvious and intentional fraud, the issues would not be sufficiently complex to require referral to HHS." (*Id.* at 9) As the government explained "some [pricing] calculations might be so obviously incorrect that they could be spotted with relatively limited expertise." (*Id.* at 12)

Petitioners' overheated rhetoric that the Court of Appeals' decision has "dramatic and sweeping con-

sequences" and creates a private right of action under the §340B statute "out of whole cloth" (Pet. 12), is wrong both under the holding of the Court of Appeals and the government's view of this case, and therefore should be viewed with skepticism. The government recognized there was a balance to be struck, and the Court of Appeals adopted it by recognizing the contract claim and not invoking primary jurisdiction. Only the petitioning Drugmakers object, as they face the prospect of being held accountable for their conduct.

Contrary to petitioners' assertion, this suit enhances rather than disrupts enforcement of both the §340B and Medicaid programs. As detailed above, the OIG reports in the record reveal, and reported cases confirm, that typically it is the manufacturers' overstatement of BP that causes both lower Medicaid rebates to the States and overcharges to covered entities in excess of the correct ceiling price for drugs purchased under the §340B program. (ER 14-15 ¶4; ER 64-67) When the correct BP is lower than the reported BP, the 340b ceiling price decreases and Medicaid rebates increase – a win-win result for both states and covered entities. As the government has acknowledged already, this suit does not disrupt government programs or warrant invocation of the agency's primary jurisdiction. Accordingly, certiorari should be denied.

CONCLUSION

For the foregoing reasons, the petition should be denied.

Respectfully submitted,

MIGUEL MÁRQUEZ
County Counsel
TAMARA LANGE
Lead Deputy County Counsel
OFFICE OF THE COUNTY COUNSEL
SANTA CLARA COUNTY
70 West Hedding, East Wing
9th Floor
San Jose, CA 95110
(408) 299-5906

SANFORD SVETCOV
Counsel of Record
JEFFREY W. LAWRENCE
SUSAN K. ALEXANDER
AELISH M. BAIG
PHILLIP G. FREEMON
ROBBINS GELLER RUDMAN & DOWD LLP
100 Pine Street
26th Floor
San Francisco, CA 94111
(415) 288-4545
sandys@rgrdlaw.com

Counsel for Respondent

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