No. 09-1273

IN THE
Supreme Court of the United States

ASTRA USA, INC., ET AL.,
Petitioners,
v.

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

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

BRIEF FOR RESPONDENT

MIGUEL MÁRQUEZ
COUNTY COUNSEL
GRETA S. HANSEN
JUNIPER L. DOWNS
JAMES R. WILLIAMS
OFFICE OF THE COUNTY COUNSEL
COUNTY OF SANTA CLARA
70 West Hedding Street
East Wing, 9th Floor
San Jose, California 95110
(408) 299-5900

DAVID C. FREDERICK
Counsel of Record
SCOTT H. ANGSTREICH
SCOTT K. ATTAWAY
KELLOGG, HUBER, HANSEN, TODD, EVANS & FIGEL, P.L.L.C.
1615 M Street, N.W.
Suite 400
Washington, D.C. 20036
(202) 326-7900
(dfrederick@khhte.com)

SANFORD SVETCOV
JEFFREY W. LAWRENCE
SUSAN K. ALEXANDER
AELISH M. BAIG
ROBBINS GELLER RUDMAN & DOWD LLP
100 Pine Street, 26th Floor
San Francisco, California 94111
(415) 288-4545

December 13, 2010

QUESTION PRESENTED

Whether, where Congress elected to implement the section 340B drug discount program through federal contracts and mandated that those contracts contain a provision making 340B entities intended third-party beneficiaries, 340B entities have a federal cause of action against drug manufacturers for their breach of that contract provision absent a more specific provision conferring a right of action on 340B entities.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page

CASES

CONSTITUTION, STATUTES, REGULATIONS, AND RULES

LEGISLATIVE MATERIALS

ADMINISTRATIVE MATERIALS

OTHER MATERIALS

INTRODUCTION

This case implicates a long-settled rule of law: when Congress by statute directs the making of contracts, "Congress expect[s] the . . . agreement[s] . . . , like ordinary contracts, to be enforceable by private suit upon a breach." *Jackson Transit Auth. v. Local Div. 1285*, 457 U.S. 15, 20-21 (1982). Such a private suit, moreover, will "state[] [a] federal claim[]" where Congress intended that "the rights and duties contained in those contracts be federal in nature." *Id.* at 23.

Those longstanding principles stand in stark contrast to situations where the Court is asked to imply a right of action in a statute in which Congress neither provided an express right of action nor required enforceable contracts. As this Court has made clear, cases involving federal contracts "do[] not fit comfortably in th[e] mold" of "private right of action case[s]." *Id.* at 20. Although petitioners and many of their *amici* labor to squeeze this case into the line of precedents involving "implied rights of action," an interpretation faithful to the language Congress actually used leads inexorably to the conclusion that respondent may sue to enforce petitioners' alleged breach of the statutorily mandated agreement.

Section 340B of the Public Health Service Act ("PHSA") aims to ensure that public hospitals, community health centers, and other providers of safety-net health services pay the same low prescription drug prices available to Medicaid. In effectuating that intent, Congress directed the Secretary of Health and Human Services ("HHS") to make "agreement[s]" with drug manufacturers limiting "the amount required to be paid . . . to the manufacturer" for drugs purchased by those "covered entit[ies]." 42

U.S.C. § 256b(a)(1). Each petitioner here signed a Pharmaceutical Pricing Agreement ("Agreement") with the Secretary; in the contract, each manufacturer "agree[d]" to "charge [340B] entities a price" that, for brand-name drugs, is normally no higher than the manufacturer's best price in the marketplace. Agreement § II(a) (App. 170a).

Following revelations stemming from federal investigations and court proceedings that manufacturers repeatedly had broken that promise, respondent County of Santa Clara sued on behalf of its 340B county medical facilities and a class of similarly situated entities, as intended third-party beneficiaries of each petitioner's Agreement. Common law from the 1600s establishes that contracts can be enforced by a class of third parties, and nothing in § 256b suggests that Congress displaced that ancient contractual remedy. As intended third-party beneficiaries, 340B entities "state[] a federal claim when [they] sue[] to vindicate contractual rights" in the Agreement, even though § 256b "lack[s] express provisions creating [a] federal cause[] of action." *Empire HealthChoice Assurance, Inc. v. McVeigh*, 547 U.S. 677, 694 (2006) (internal quotations omitted).

All but ignoring this Court's longstanding rulings regarding the enforcement of federal contracts, petitioners and their *amici* — except, notably, the United States — argue that the lack of an express or implied cause of action to enforce the statute is dispositive. But the fundamental flaw in that approach is that it nullifies Congress's decision to mandate that the Secretary and drug manufacturers enter into what petitioners and their industry association concede are "federal contract[s]." Pet. Br. 42; *see also id.* at i; PhRMA Br. 2, 9. On their view, § 256b is no different

from a statutory mandate, implemented through notice-and-comment rulemaking, that conditions a manufacturer's inclusion in Medicaid on its willingness to sell to 340B entities at reduced prices. But Congress instead chose to use contracts and, moreover, did not create any administrative remedy that might displace longstanding common-law contract remedies for intended third-party beneficiaries.

The United States implicitly recognizes that petitioners' reliance on this Court's implied-right-of-action jurisprudence is misplaced. Instead, it offers novel arguments outside the Question Presented that petitioners have waived and that, on their own terms, lack merit. The United States first erroneously denies that the Agreement is an enforceable contract, notwithstanding petitioners' concession that the Agreement is a contract. The United States then attempts to resuscitate an argument (waived by petitioners in the certiorari petition) that 340B entities are not intended third-party beneficiaries under the Agreement. The terms Congress mandated that the Secretary include in the Agreement clearly identify 340B entities as intended beneficiaries of manufacturers' promise to cap the prices at which they sell drugs to 340B entities, consistent with settled common-law principles.

Respondent's breach-of-contract remedy both advances Congress's design to provide the best prices to entities that serve the poor and complements federal government enforcement efforts that have been insufficient. Such parallel suits "enforce federal . . . requirements" and "aid, rather than hinder, the functioning of [federal statutes]." *Bates v. Dow Agro-Sciences LLC*, 544 U.S. 431, 451 (2005).

STATEMENT

1. Although "Medicaid is the Nation's largest single purchaser of prescription drugs," before 1990 "it usually pa[id] the highest prices" for those drugs,[1] while "other large purchasers received discounts from drug manufacturers."[2] For example, Medicaid paid $29 for a bottle of Motrin that cost a typical hospital only $8 and the Department of Veterans Affairs only $5.[3] Already high prescription drug costs were growing much faster than other Medicaid expenditures.[4]

Congress found that state of affairs intolerable, not only because Medicaid's purchasing power ought to garner the best discounts available in the market, but also because Medicaid uses scarce federal and state taxpayer dollars to provide safety-net medical care to the most vulnerable individuals. Congress was concerned that States — which pay a portion of Medicaid costs — might respond to skyrocketing drug costs by curtailing Medicaid beneficiaries' access to needed medications.[5]

---

[1] Melvina Ford, Congressional Research Service Report for Congress, *Medicaid: Reimbursement for Outpatient Prescription Drugs*, CRS-17 (Mar. 7, 1991) ("Ford").

[2] Ford at CRS-15; *see also* H.R. Rep. No. 101-881, at 96 (1990) ("1990 House Report"), *reprinted in* 1990 U.S.C.C.A.N. 2017; *Skyrocketing Prescription Drug Prices*, S. Hrg. 101-747 (1990); *Medicaid Budget Initiatives*, H. Hrg. 101-206 (1991); *Medicaid Prescription Drug Pricing*, S. Hrg. 101-1261 (1991).

[3] *See Skyrocketing Drug Prices* at 4; *id.* at 33-40; Ford at CRS-17.

[4] *See Pharmaceutical Research & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 649 n.1 (2003).

[5] *See* Ford at CRS-15.

To ensure that Medicaid has "the benefit of the best price" available in the marketplace, Congress enacted the Medicaid Rebate Program in 1990.[6] *See* 42 U.S.C. § 1396r-8.[7] Congress compelled manufacturers seeking to sell drugs to Medicaid patients to "enter[] into and have in effect a rebate agreement" with the Secretary of HHS (or, at the Secretary's discretion, with a State); that contract would require the manufacturer to rebate to States a portion of the purchase price of prescription drugs. § 1396r-8(a)(1), (b)(1)(A).[8] Only with such a contract in place would federal Medicaid funds be available to pay a portion of the States' prescription drug costs. *See* §§ 1396b, 1396r-8(a)(1).

2. Manufacturers responded to the new Medicaid contracts by *raising* their "'best prices' on covered outpatient drugs that Medicaid patients use in any significant volume," thereby minimizing the cost of rebates due to the States.[9] Hardest hit by those price increases were "[f]ederally-funded clinics and public

---

[6] 1990 House Report at 96.

[7] Unless otherwise noted, statutory citations below are to Title 42. Congress amended both the Medicaid and 340B program statutes in the Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010) ("PPACA"). References herein are to the pre-PPACA Medicaid and 340B program statutes, unless otherwise noted.

[8] Congress recognized that certain larger States, like California, already had negotiated their own contracts with certain manufacturers for discounts for their state Medicaid programs. Congress preserved those contracts, so long as they provided benefits equivalent to those under the new rebate contracts. *See* § 1396r-8(a)(4).

[9] H.R. Rep. No. 102-384(II), at 9 (1992) ("1992 House Report").

hospitals serving large numbers of low-income patients."[10]

In 1992, Congress responded to manufacturers' price hikes by enacting section 340B of the PHSA, 42 U.S.C. § 256b,[11] through which it expanded both the contract regime and the best-price provisions it had adopted for Medicaid. Specifically, Congress required the Secretary to "enter into an agreement with each manufacturer" that sells drugs reimbursed by Medicaid; that contract would cap the price the manufacturer could charge to any 340B "covered entity." § 256b(a)(1). *See* 1992 House Report at 7, 12 (explaining that a specific purpose of section 340B was "to enable . . . certain Federally-funded clinics to obtain lower prices on the drugs that they provide to their patients" and that "[i]n giving these 'covered entities' access to price reductions the Committee intends to enable these entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services").

340B covered entities include public hospitals and community health centers that provide safety-net services, among others.[12] Such entities must take steps to prevent issuance of Medicaid rebates for drugs that manufacturers sell to 340B entities at a discount pursuant to an Agreement. *See* § 256b(a)(5). Congress directed HHS to "establish a mechanism" to enforce that prohibition; 340B entities may be "liable to the manufacturer" to refund the discount

---

[10] *Id.* at 10.

[11] *See* Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602, 106 Stat. 4943, 4967-71.

[12] *See* § 256b(a)(4) (defining "covered entity").

provided under the Agreement. § 256b(a)(5)(A)(ii), (D). Congress described that discount as having been "provided under the agreement *between the entity and the manufacturer* under this paragraph" — that is, under the Agreement. § 256b(a)(5)(D) (emphasis added).

To implement the 340B program, the Secretary drafted the Agreement, which it sent to manufacturers in December 1992 for their signature. App. 165a-181a.[13] By signing the Agreement, a "[m]anufacturer agrees" to "charge covered entities a price . . . that does not exceed" a ceiling price. Agreement § II(a)-(b). For "a single source drug or innovator multiple source drug" — that is, brand-name drugs[14] — the discounted price is typically the manufacturer's "best price." The statute defines "best price" to mean the "lowest price available" in the marketplace (with certain exceptions), after accounting for any "cash discounts, free goods that are contingent on any purchase requirement, volume discounts, and rebates." § 1396r-8(c)(1)(C)(i); *see* Agreement § I(b).[15]

---

[13] *See also* 58 Fed. Reg. 27,289, 27,291 (May 7, 1993).

[14] *See* 42 C.F.R. § 447.502 ("*Brand name drug* means a single source or innovator multiple source drug.").

[15] The minimum discount for a brand-name drug is 15.1% off the "average manufacturer price" or "AMP" of a drug, and 11% off the AMP of other drugs. *See* § 1396r-8(c)(1)(B), (c)(3)(B); Agreement § II(a)-(b). The AMP is simply the average price paid nationwide for a drug by wholesalers that distribute drugs to retail pharmacies. *See* § 1396r-8(k)(1); Agreement § I(a). In sum, "the 340B ceiling price . . . equals the Medicaid net manufacturer price." Congressional Budget Office, *Prices for Brand-Name Drugs Under Selected Federal Programs* 12 (June 2005), http://www.cbo.gov/ftpdocs/64xx/doc6481/06-16-PrescriptDrug.pdf.

As enacted, section 340B contained no administrative dispute resolution process — informal or otherwise — although Congress authorized the Secretary to terminate an Agreement "for violation of the requirements of the agreement." § 1396r-8(b)(4)(B)(i), (v). The Agreement, however, provides that the Secretary "may initiate [an] informal dispute resolution process" if it "believes that the Manufacturer" has breached the Agreement, through which the Secretary "may require the Manufacturer to reimburse [a covered] entity for discounts withheld." Agreement § IV(c). The Agreement provides that this informal process does not "preclude . . . the Secretary from exercising such other remedies as may be available by law" to remedy a breach of the Agreement. *Id.* § IV(e). HHS also has a generally applicable informal dispute process, but similarly has made clear that "[n]o manufacturer or covered entity is required to avail itself of" that process "before resorting to other available measures." 61 Fed. Reg. 65,406, 65,411 (Dec. 12, 1996).[16]

3. Despite the plain terms of their Medicaid contracts and the Agreement, drug manufacturers repeatedly have overcharged 340B entities and Medi-

---

[16] Congress recently amended § 256b to require the Secretary to establish a formal dispute resolution process for sales to covered entities on or after January 1, 2010. *See* PPACA §§ 7101(e), 7102(a), 124 Stat. 823, 826 (codified at § 256b(d)(3)). Congress directed the Secretary to "promulgate regulations" to create this administrative process within 180 days — or by September 19, 2010. *Id.* § 7102(a), 124 Stat. 826 (codified at § 256b(d)(3)(A)). The Secretary did not meet that deadline. Instead, on September 20, 2010, the Secretary issued an advanced notice of proposed rulemaking seeking comment on 13 areas to inform its development of proposed regulations. *See* 75 Fed. Reg. 57,233 (Sept. 20, 2010).

caid by disguising the best prices for their brand-name drugs. Those schemes have come to light through whistleblower complaints filed under the False Claims Act ("FCA").

In one scheme — known as "lick and stick" — drug manufacturers sold heavily discounted drugs to health maintenance organizations, which resold the drugs at retail under a private label. Manufacturers excluded those re-branded discounted sales from the best prices reported to HHS. Following disclosure by a whistleblower of one such "lick and stick scheme," petitioner Bayer settled FCA charges and pleaded guilty to criminal charges, paying $257 million.[17] Whistleblower suits likewise caused petitioners GlaxoSmithKline to pay $87 million,[18] Bristol-Myers Squib to pay $515 million, and Aventis to pay $95.5 million, in whole or in part to settle claims based on similar schemes.[19] Only a small portion of those settlement dollars went to reimburse 340B entities that overpaid those manufacturers.

In another scheme, manufacturers provided purchasers with "off-invoice price concessions" — or kickbacks — tied directly to the purchase of the drugs. Manufacturers, however, excluded the value

---

[17] HHS/DOJ Health Care Fraud and Abuse Control Program, *Annual Report for FY 2003* (Dec. 2004), http://oig.hhs.gov/publications/docs/hcfac/hcfacreport2003A.htm.

[18] *See id.*

[19] *See* DOJ Press Release, *Bristol-Myers Squibb to Pay More Than $515 Million to Resolve Allegations of Illegal Drug Marketing and Pricing* (Sept. 28, 2007), http://www.justice.gov/opa/pr/2007/September/07_civ_782.html; DOJ Press Release, *Aventis Pharmaceutical to Pay U.S. $95.5 Million to Settle False Claims Act Allegations* (May 28, 2009), http://www.justice.gov/opa/pr/2009/May/09-civ-520.html.

of those concessions (including cash, grants, and trips, among others) in calculating the best prices for those drugs.[20] Again, whistleblowers revealed these schemes, which led to guilty pleas, settlements, and payments by petitioners TAP Pharmaceuticals of $875 million, Merck of $650 million, AstraZeneca of $355 million, Schering-Plough of $345 million, and Pfizer of $49 million.[21] And, again, 340B entities received little of that money.

In still another scheme, manufacturers have sought to evade the Agreement provision pertaining to bundled sales, which requires the manufacturer to allocate the discounts provided on each drug across all drugs in the bundle. *See*, *e.g.*, Agreement § I(a), (c). Manufacturers repeatedly have excluded contracts offering bundles of drugs in calculating their best prices. Following whistleblower revelations, the United States and more than 30 States currently are pursuing claims for hundreds of millions of dollars

---

[20] DOJ Press Release, *AstraZeneca Pharmaceuticals LP Pleads Guilty to HealthCare Crime; Company Agrees to Pay $355 Million to Settle Charges* (June 20, 2003), http://www.justice.gov/opa/pr/2003/June/03_civ_371.htm.

[21] *See id.*; DOJ Press Release, *TAP Pharmaceutical Products Inc. and Seven Others Charged With Health Care Crimes; Company Agrees to Pay $875 Million to Settle Charges* (Oct. 3, 2001), http://www.justice.gov/opa/pr/2001/October/513civ.htm; DOJ Press Release, *Schering-Plough to Pay $345 Million to Resolve Criminal and Civil Liabilities for Illegal Marketing of Claritin* (July 30, 2004), http://www.justice.gov/opa/pr/2004/July/04_civ_523.htm; DOJ Press Release, *Drug Giant Pfizer & Two Subsidiaries to Pay $49 Million for Defrauding Drug Medicaid Rebate Program* (Oct. 28, 2002), http://www.justice.gov/opa/pr/2002/October/02_civ_622.htm; DOJ Press Release, *Merck to Pay More than $650 Million to Resolve Claims of Fraudulent Price Reporting and Kickbacks* (Feb. 7, 2008), http://www.justice.gov/opa/pr/2008/February/08_civ_094.html.

against petitioner Wyeth for failing to include bundled sales in calculating the best price of its drug Protonix,[22] which brought in revenues of nearly $2 billion in 2007.[23]

4. Federal administrative efforts to rectify manufacturers' violations of their best-price duties have been virtually non-existent. The HHS Office of the Inspector General ("OIG") repeatedly has found that neither the Health Resources and Services Administration ("HRSA"), which administers the 340B program, nor the Centers for Medicare & Medicaid Services ("CMS"), which administers the Medicaid Rebate Program, has the staff or budget necessary to ensure that manufacturers comply with the terms of the Agreement with respect to the 35,000 drugs (*see* Pet. Br. 34) covered under the Agreement.

For example, a March 2003 OIG report found that, in 1998 and 1999, five manufacturers had used "lick and stick" schemes to overcharge 340B entities by $6.1 million on only $13.7 million of sales.[24] Despite HRSA's commitment to take action against these

---

[22] *See, e.g.*, Complaint, *United States ex rel. Kieff v. Wyeth*, Nos. 03-12366-DPW & 06-11724-DPW (D. Mass. filed May 18, 2009); Amended Complaint of the States and the District of Columbia, *United States ex rel. Kieff v. Wyeth*, Nos. 03-12366-DPW & 06-11724-DPW (D. Mass. filed Oct. 9, 2009).

[23] *See* Wyeth 2007 Financial Report at 65, http://sec.gov/Archives/edgar/data/5187/000119312508042780/dex13.htm.

[24] *See* OIG, *Pharmaceutical Manufacturers Overcharged 340B-Covered Entities*, A-06-01-00060, at 1, 3-4 (Mar. 2003), ftp://ftp.hrsa.gov/bphc/pdf/opa/A-06-01-00060.pdf.

manufacturers,[25] nearly three years later, overcharged 340B entities still were waiting for refunds.[26]

A June 2004 OIG report, later withdrawn because of problems with CMS and HRSA data, concluded that covered entities had overpaid $41.1 million in a single month.[27] In September 2005, Senator Charles Grassley, then-Chairman of the Senate Finance Committee, wrote to HRSA expressing concern, based in part on the OIG reports, with "systemic problems in the 340B program."[28]

An October 2005 OIG report similarly identified "systemic problems with the accuracy and reliability of the Government's record of the 340B ceiling price," including the fact that neither CMS nor HRSA had "established written procedures . . . for calculating the 340B ceiling price."[29] OIG also found that "no one has engaged in" HRSA's "voluntary process for resolving disputes between manufacturers and

---

[25] *Id.* App. A.

[26] *See Oversight and Administration of the 340B Drug Discount Program: Improving Efficiency and Transparency*, H. Hrg. 109-108, at 17 (2006) ("*2006 Oversight Hearing*") (prepared statement of Dennis Williams, Deputy Administrator, HRSA), http://www.gpo.gov/fdsys/pkg/CHRG-109hhrg30139/pdf/CHRG-109hhrg30139.pdf.

[27] *See* OIG, *Appropriateness of 340B Drug Prices*, OEI-05-02-00070, at 5 (June 2004) (C.A. E.R. 74-102); Withdrawal Notice (Oct. 21, 2004), http://www.oig.hhs.gov/oei/reports/oei-05-02-00070.pdf.

[28] Letter from Sen. Charles E. Grassley to Elizabeth M. Duke, Administrator, HRSA at 2-4 (Sept. 1, 2005), http://www.drugdiscountmonitor.com/members/HRSA_Letter.pdf.

[29] OIG, *Deficiencies in the Oversight of the 340B Drug Pricing Program*, OEI-05-02-00072, at ii, 10, 12 (Oct. 2005) ("2005 Deficiencies Report"), http://oig.hhs.gov/oei/reports/oei-05-02-00072.pdf.

[340B] entities."[30] Indeed, even where HRSA analysts discovered that manufacturers were charging prices greater than the ceiling price, "HRSA did not initiate the dispute resolution process or take other action to resolve this issue."[31]

Although the October 2005 OIG report did not "review CMS's oversight of [the] manufacturer-reported prices" used to calculate the best prices available to both Medicaid and 340B entities,[32] a February 2005 Government Accountability Office ("GAO") report had found that CMS was conducting only "minimal oversight" of "manufacturer-reported prices."[33] GAO determined that "CMS does not generally check to ensure that manufacturers' assumptions and price determination methods are consistent with the rebate statute and rebate agreement."[34] Moreover, "CMS does not verify" that manufacturers comply with their obligation to "maintain [the] documentation underlying" the reported average manufacturer prices ("AMPs") and best prices, and "rarely requests" that information from manufacturers.[35] Although the GAO report recommended that CMS implement

---

[30] *Id.* at 16.

[31] *Id.* at 17. In a July 2006 report, the OIG found evidence that manufacturers had overcharged a group of 340B entities a total of $3.9 million in a single month. *See* OIG, *Review of 340B Prices*, OEI-05-02-00073, at 11 (July 2006) ("2006 Overcharge Report"), http://oig.hhs.gov/oei/reports/oei-05-02-00073.pdf.

[32] 2005 Deficiencies Report at 8; *see id.* at 4-5.

[33] GAO, Medicaid Drug Rebate Program, *Inadequate Oversight Raises Concerns about Rebates Paid to States*, GAO-05-102, at 10 (Feb. 2005) ("2005 Inadequate Oversight Report"), http://www.gao.gov/new.items/d05102.pdf.

[34] *Id.* at 11.

[35] *Id.*

"systematic oversight" of manufacturer-reported prices,[36] a September 2010 OIG report found that CMS still "do[es] not currently have the resources to pursue" manufacturers that submit incomplete pricing reports, let alone to request (or to review) the contracts, invoices, and other documents needed to verify manufacturers' reported best prices.[37]

5. Respondent County of Santa Clara owns, operates, and provides health services through numerous county medical facilities that are 340B entities. *See* JA28-30 (¶ 1) ("Complaint"). Like all California counties, Santa Clara is required to act as the healthcare "'provider of last resort'" to its indigent residents. JA34 (¶ 13) (quoting Cal. Welf. & Inst. Code § 17000). From 2003 through 2005, Santa Clara's 340B entities spent approximately $90 million on drugs sold under the Agreement. *See* JA30, 45-47 (¶¶ 3, 46).

Relying on the revelations of manufacturer overcharges detailed above, Santa Clara brought suit on behalf of its 340B entities[38] and a class of similarly situated entities, alleging that the petitioner drug manufacturers have charged them more than the 340B ceiling price for covered drugs. *See* JA28-32, 47-56 (¶¶ 1, 4-7, 47-71).[39] Santa Clara's complaint raised several claims, but the single claim before this

---

[36] *Id.* at 23.

[37] OIG, *Drug Manufacturers' Noncompliance With Average Manufacturer Price Reporting Requirements*, OEI-03-09-00060, at 14 (Sept. 2010) ("2010 Noncompliance Report"), http://oig.hhs.gov/oei/reports/oei-03-09-00060.pdf.

[38] The County's 340B entities lack independent authority to sue under state law. *See* App. 104a.

[39] The petitioner drug manufacturers' annual sales range from $5.8 billion to $16.5 billion. *See* JA35-40 (¶¶ 16-26).

Court is for petitioners' breach of the Agreement with the Secretary. *See* JA63-64 (¶¶ 101-104). Santa Clara alleges that it is an intended third-party beneficiary of those contracts, in which petitioners each agreed, "[p]ursuant to requirements under section 340B," "to charge covered entities a price for each unit of the drug that does not exceed [the ceiling price]." Agreement § II(a).[40]

The district court found that 340B entities are intended third-party beneficiaries under the Agreement, because the Agreement (as § 256b requires) compels manufacturers to provide discounts to 340B entities, thus "suggest[ing] that Congress intended to benefit them directly." App. 117a. The court, however, held that even an intended third-party beneficiary cannot sue to enforce a contract without an affirmative indication authorizing such a suit. *Id.* Not finding such a statement in the Agreement or the statute, the court dismissed Santa Clara's contract claim.

6. On appeal, the Ninth Circuit reversed. "Applying the federal common law of contracts," the court of appeals first agreed with the district court that 340B entities "are intended direct beneficiaries of the[] [Agreement]." App. 31a. The court recognized that "[d]emonstrating third-party beneficiary status in the context of a government contract is a comparatively difficult task" because "parties that benefit from a government contract are generally assumed to be incidental beneficiaries," which normally may not

---

[40] Plaintiffs sought leave to move for certification of a nationwide class, which the district court denied without prejudice as premature. *See* Third Amended Case Management Order at 4 (Dkt. Entry 667).

sue to enforce the contract. App. 38a (internal quotations and alteration omitted).

In finding that 340B entities are intended, not incidental, beneficiaries under the Agreement, the Ninth Circuit reasoned that "Manufacturers undertook a specific responsibility to the covered entities: 'Pursuant to [§ 256b], the Manufacturer *agrees* . . . to charge *covered entities* a price for each unit of the drug that does not exceed' the ceiling price of that drug. *See* [Agreement] § II(a) (emphasis added)." App. 41a; *see* App. 41a-42a (reading § II(a) as "an unambiguous, concrete limitation on how much the Manufacturers may charge the covered entities"). The court concluded that, on "a fair reading of the [Agreement], we are unable to discern any substantial purpose of the [Agreement] *other* than to grant eligible covered entities a discount on covered drugs." App. 42a-43a.

The court found support for its conclusion that 340B entities are the intended beneficiaries of this provision in the legislative history, which makes clear that Congress enacted § 256b "'to *enable* . . . *certain Federally-funded clinics [i.e., covered entities] to obtain lower prices* on the drugs that they provide to their patients'" and "'to *enable these entities* to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.'" App. 43a-44a (quoting 1992 House Report at 7, 12) (emphasis and alterations by the court).

The Ninth Circuit disagreed with the district court's conclusion that something more was needed for 340B entities to sue to enforce the Agreement. Rather, "the right to sue inheres in one's status as an intended beneficiary." App. 39a (citing, *inter alia*,

Restatement (Second) of Contracts § 304 (1981) ("Restatement") ("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.")).

The court next rejected petitioners' contention that the absence of a private, statutory right of action to enforce § 256b precluded 340B entities from suing to enforce the contracts. App. 50a-55a.[41] The court, however, recognized that the correct question is whether Congress, by statute, had "displace[d]" the "federal common law contract remedy that the covered entities could invoke as intended beneficiaries of the [Agreement]." App. 51a, 54a. Reviewing the statute, the court found "[n]othing" to "suggest[] that Congress intended" to displace that common-law contract remedy; instead, such suits are "wholly compatible with the Section 340B program's objectives." App. 54a-55a. Petitioners did not petition for certiorari from the Ninth Circuit's 2008 decision.

7. On remand, Santa Clara sought discovery of information necessary to verify the manufacturers' reported best prices of their brand-name drugs, as such information is not publicly available and, as GAO and OIG had found, is rarely (if ever) disclosed to HHS. The manufacturers moved for a protective order, relying on a sentence in part of the Ninth Circuit's discussion of primary jurisdiction stating that the Agreement entitles 340B entities only "to the average manufacturer price *reported* to the Secretary; they cannot claim that the reported figure was itself somehow erroneous." App. 57a. The district

---

[41] Santa Clara conceded below that there is no federal private right of action pursuant to § 256b, which the court of appeals assumed without deciding. *See* App. 50a & n.15.

court reluctantly issued the protective order, stating that, but for the Ninth Circuit's statement, it "would be inclined" to order the requested discovery. App. 90a. It reasoned that, to comply with the Agreement, manufacturers had to charge a price that did not exceed a ceiling price calculated using correctly reported best-price and AMP information. App. 91a.

The district court *sua sponte* certified its ruling for interlocutory appeal, which the Ninth Circuit accepted. App. 2a n.**. After receiving briefs from the parties, the Ninth Circuit sought the views of the United States as *amicus curiae*. The United States agreed with the district court that the contract required manufacturers to charge no more than a ceiling price calculated "using only accurately reported" best prices and AMPs. U.S. C.A. Amicus Br. 17 (Oct. 27, 2009). The United States nevertheless supported the district court's ruling, asserting that 340B entities should not be permitted to sue as intended third-party beneficiaries. *See id.* at 17-21. In the event the district court were reversed, however, the United States argued that the court of appeals "should refrain from invoking primary jurisdiction now," explaining 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.* at 13-14; *see id.* at 25 ("No special agency expertise is implicated by such straightforward claims.").

Rather than proceed to argument and decision on the interlocutory appeal, the Ninth Circuit recalled the mandate on its original opinion. The court issued a superseding opinion, in which it altered only its discussion of primary jurisdiction. In the revised opinion, the court deleted the sentence on which the

manufacturers had relied to oppose discovery and noted that any primary jurisdiction referral was premature. *See* App. 28a-29a.

8. Following the Ninth Circuit's revised ruling, respondent began to obtain discovery into the manner in which petitioners calculated the best prices they reported to HHS. The district court exercised significant supervision over that discovery, limiting the initial phase to certain categories of information and depositions. *See* App. 74a-78a. As a result, the case has been pared down to a separate trial against each defendant, involving their top three to five drugs. After this Court granted the certiorari petition, the district court stayed the case, suspending the discovery (virtually all of which has been produced pursuant to a protective order) that had been proceeding into the information necessary to prove that petitioners have breached the Agreement by charging 340B entities more than the best prices for brand-name drugs.

SUMMARY OF ARGUMENT

I.A. Congress required the Secretary and manufacturers to enter an "agreement" to implement § 256b. That Agreement is an enforceable federal contract. This Court's longstanding precedents establish that, when Congress employs contracts as the means of effectuating a statute, it intends for those agreements, "like ordinary contracts, to be enforceable by private suit upon a breach," regardless of the proper forum for such claims. *Jackson Transit*, 457 U.S. at 20-21. For nearly a century, this Court has held "that a plaintiff state[s] a federal claim when he sue[s] to vindicate contractual rights *set forth by federal statutes*, [even though] the relevant statutes lacked express provisions creating federal causes of

action." *Empire HealthChoice*, 547 U.S. at 694 (internal quotations omitted; emphasis and third alteration in original). Here, respondent's claim that petitioners violated the Agreement's ceiling price states a federal-law claim, both because the Agreement is a "federal contract," Pet. Br. 42, and because the United States is a party to the contract.

B. In selecting contracts as its mechanism for implementing § 256b and benefiting 340B entities, Congress evinced no intent to depart from standard common-law contract principles. For more than 350 years, those common-law principles have authorized certain third-party beneficiaries (now known as intended beneficiaries) to sue to enforce a contractual promise made by a party to the contract for the intended beneficiary's special benefit. As both courts below found, 340B entities are intended third-party beneficiaries of the congressionally mandated Agreement provision requiring manufacturers to "charge *covered entities* a price . . . that does not exceed" the ceiling price. Agreement § II(a) (emphasis added). The statutory text also contains Congress's reference to the Agreement as one "between the [340B] entity and the manufacturer," § 256b(a)(5)(D), and the legislative history supports the conclusion that 340B entities are intended beneficiaries of the Agreement. Only in 2010 — well after respondent's suit was brought — did Congress enact a statutory remedy that could be thought to displace the standard common-law remedy available to intended third-party beneficiaries.

II. Neither petitioners nor the United States provide a basis for ignoring Congress's decision to implement § 256b through enforceable contracts.

A. Petitioners and their *amici* — except for the United States — erroneously rely on this Court's implied private right of action cases. As this Court has concluded, cases such as this one, which seek to enforce provisions in a federal contract, "do[] not fit comfortably in th[e] mold" of "private right of action case[s]." *Jackson Transit*, 457 U.S. at 20. Indeed, under petitioners' theory, § 256b is no different from a statute that requires discounts to covered entities through statutory directives and agency notice-and-comment rulemaking. Under petitioners' reading, Congress's decision to implement § 256b through federal contracts was a completely meaningless legislative choice.

B. The United States alone asserts that the Agreement is not a contract because it implements a regulatory scheme. That claim is both outside the scope of the Question Presented and unpersuasive. A four-Justice plurality rejected a similar attempt to distinguish "regulatory" contracts from other contracts, explaining that such a distinction "would flout the general principle that, when the United States enters into contract relations, its rights and duties therein are governed generally by the law applicable to contracts between private individuals." *United States v. Winstar Corp.*, 518 U.S. 839, 895 (1996) (plurality) (internal quotations and alteration omitted). The authorities on which the United States relies show only that Congress's intent is highly relevant to the interpretation of contracts mandated by statute. None holds that such contracts are unenforceable through traditional, well-settled contractual remedies. The United States also erroneously seeks to read the 2010 enactment of the PPACA as evidence of Congress's intent in 1992. This Court

long has made clear that such subsequent enactments shed no light on the intent of a previous Congress.

C. Despite petitioners' waiver of the argument, the United States challenges respondent's status as an intended third-party beneficiary of the Agreement. But the United States' focus on whether the *Secretary* intended to permit 340B entities to sue to enforce manufacturers' promise in the Agreement is misplaced. The relevant intent is that of *Congress*, which mandated that the Secretary draft a contract requiring manufacturers to promise to charge 340B entities no more than the ceiling price. Under long-settled contract-law principles, such a provision gives rise to a federal cause of action by 340B entities to enforce that promise as intended third-party beneficiaries.

III.A. Suits by 340B entities are fully compatible with federal enforcement efforts, as they seek to enforce the same promises manufacturers made in signing the Agreement. As the United States has emphasized in previous cases, courts are well-suited to adjudicate claims that a manufacturer has breached its obligations with respect to drug prices. In addition, primary jurisdiction referrals to the agency are available where necessary, although many cases of best-price manipulation, such as those revealed previously through whistleblower suits, will not require the agency's special expertise.

Moreover, as the United States elsewhere has explained, it would be "unreasonable" to place on the Secretary "sole responsibility for monitoring best price fraud." U.S. Amicus Br. at 14, *In re Pharm. Indus. Average Wholesale Price Litig.*, No. 01-CV-12257-PBS (D. Mass. filed Mar. 18, 2004)

("U.S. *Mass.* Amicus Br."). HHS neither receives nor reviews the sales contracts and other documents that would reveal manufacturers' improper exclusion of rebranded sales, kickbacks, or bundled discounts from reported best prices. Thus, it makes no sense to assert, as the United States does here, that Congress intended HHS to be the exclusive enforcer of compliance with the Agreement, particularly when drug manufacturer breaches of the best-price provision directly injure 340B entities.

B. As myriad government reports have found, HHS is ill-equipped to enforce the best-price requirement in the Agreement and, when presented with solid evidence of violations, often has failed to remedy them. Indeed, although petitioners and the United States point to actions HHS "may" take to remedy manufacturer overcharges, they identify no actions HHS actually has taken to protect 340B entities and the public fisc. Indeed, the primary means of enforcement to date have been whistleblowers' suits under the False Claims Act. But waiting for employee whistleblowers to file *qui tam* suits is hardly a reliable means of enforcing the Agreement. Such suits rest on the fortuity of an internal watchdog who can ferret out evidence of fraudulent intent in sales reflecting alleged overpayments by 340B entities. Those 340B entities — which Congress intended to benefit and which are directly affected by manufacturer overcharges — are well-situated to enforce the Agreement. Actions by such entities complement federal enforcement efforts and enable 340B entities to stretch scarce resources farther in providing needed medicine to the poor.

ARGUMENT

I. CONGRESS'S DECISION TO IMPLEMENT § 256B THROUGH FEDERAL CONTRACTS THAT CREATE THIRD-PARTY BENEFICIARY RIGHTS GIVES 340B ENTITIES A FEDERAL CAUSE OF ACTION TO ENFORCE THE AGREEMENT

A. A Federal Contract Is Enforceable Through A Federal Cause Of Action Regardless Of Whether A Statute Provides A Private Right Of Action

1. Section 256b(a)(1) requires an "agreement" and thus plainly contemplates an enforceable contract. "In determining whether a law tenders a contract to a citizen, it is of first importance to examine the language of the statute." *Dodge v. Board of Educ.*, 302 U.S. 74, 78 (1937). Where, as here, the statutory language "provides for the execution of a written contract on behalf of the state, the case for an obligation binding upon the state is clear." *Id.* Congress's use of "agreement" in § 256b is synonymous with "contract," because the "agreement" between the Secretary and manufacturers is supported by the mutual assent and consideration required to create an enforceable contract. *See Grafton v. Cummings*, 99 U.S. 100, 110 (1878) ("agreement . . . signif[ies] a mutual contract on consideration between two or more parties"). This Court has treated "contract" and "agreement" as interchangeable terms. *See Rent-A-Center, West, Inc. v. Jackson*, 130 S. Ct. 2772, 2776-77 (2010) (using "agreement" and "contract" interchangeably in discussing Federal Arbitration Act); *see also* Restatement § 1 cmt. a (describing "agreement" and "contract" as "synonym[s]").

For nearly a century, this Court has held repeatedly "'that a plaintiff state[s] a federal claim when he sue[s] to vindicate contractual rights *set forth by federal statutes*, [even though] the relevant statutes lacked express provisions creating federal causes of action.'" *Empire HealthChoice*, 547 U.S. at 694 (quoting *Jackson Transit*, 457 U.S. at 22) (emphasis and third alteration in original). In *American Surety Co. v. Schultz*, 237 U.S. 159 (1915), for example, this Court considered whether a third party's breach-of-contract claim on a supersedeas bond stated a federal cause of action, where a federal statute required posting of the bond before pursuing a federal court appeal. The Court explained that "there would seem to be no doubt on the subject" because "the measure of . . . recovery [on the bond] depended upon the construction to be given the Federal statute." *Id.* at 160-61.

In recent decades, this Court has reaffirmed the longstanding principle that congressional statutes directing the formation of contracts evince the requisite intent for such contracts to be enforceable in private actions. In *International Association of Machinists v. Central Airlines, Inc.*, 372 U.S. 682 (1963), for example, the Court construed 45 U.S.C. § 184, in which Congress had compelled air carriers to enter into "agreement[s]" with their unionized employees to implement congressional policy regarding the settlement of employee grievances. *Id.* at 690. Finding such agreements "legally enforceable in the [federal] courts," the Court reasoned that the union's action alleging the breach of one such contract stated a federal claim, as "[t]he contracts and the adjustment boards for which they provide are creations of federal law and bound to the statute and its policy." *Id.* at

690, 692. Because the "contract[] is a federal contract [it] is therefore governed and enforceable by federal law, in the federal courts." *Id.*[42]

Similarly, in *Norfolk & Western Railway Co. v. Nemitz*, 404 U.S. 37 (1971), this Court affirmed the Sixth Circuit's ruling that railway employees had a federal cause of action to enforce a contract between two merging railroads and their employees' unions. In 49 U.S.C. § 5(2)(f) (1970), Congress had required the Interstate Commerce Commission to review and approve that contract before authorizing the merger. *See id.* at 40-43 (affirming 436 F.2d 841 (6th Cir. 1971)). And in *Transamerica Mortgage Advisors, Inc. v. Lewis*, 444 U.S. 11 (1979), the Court concluded that, by declaring in 15 U.S.C. § 80b-15 that certain contracts "shall be void," Congress "intended that the customary legal incidents of voidness would follow, including the availability of a suit for rescission or for an injunction against continued operation of the contract, and for restitution." *Id.* at 19. The Court therefore found that a suit to void such a contract stated a federal claim, *see id.* at 18, even though "the statute itself made no express provision for private suits," *Jackson Transit*, 457 U.S. at 22 (describing *Transamerica*).

This Court also repeatedly has found it appropriate to assume that Congress "expected the [statutory] agreement . . . , like [an] ordinary contract[], to be

---

[42] *See also Verizon Maryland Inc. v. Global NAPs, Inc.*, 377 F.3d 355, 364-65 (4th Cir. 2004) (relying on *Central Airlines* to hold that action to enforce contract mandated by 47 U.S.C. §§ 251-252 states federal claim, where such contracts are "the vehicles chosen by Congress to implement the duties imposed in § 251" and the "specific duty" in the contract claimed to be breached "ha[s] a direct connection to the Act").

enforceable by private suit upon a breach." *Id.* at 20-21; *see Mobil Oil Exploration & Producing S.E., Inc. v. United States*, 530 U.S. 604, 607 (2000) ("When the United States enters into contract relations, its rights and duties therein are governed generally by the law applicable to contracts between private individuals.") (internal quotations omitted); *Transamerica*, 444 U.S. at 19 (Congress "intend[s] that the customary legal incidents of [contracts] follow").

Accordingly, where Congress "intended" that statutorily required "agreements be 'creations of federal law'" and that the "rights and duties contained in those contracts be federal in nature," a suit to enforce such a contract "states [a] federal claim[]." *Jackson Transit*, 457 U.S. at 23 (quoting *Central Airlines*, 372 U.S. at 692, 695).

2. The proposition that congressionally mandated contracts are enforceable through private actions is so well-settled that, in recent cases, the issue before this Court has been whether such actions can be pursued in federal or state forums. *Jackson Transit* thus involved a union's claim that a local transit authority had breached a contract that Congress required the authority to sign in order to receive federal funds. *See* 457 U.S. at 16-18 (discussing 49 U.S.C. § 1609(c) (1982)). Relying on the legislative history, because the "bare language of [the statute] is not conclusive," *id.* at 23, the Court found that Congress had intended for the contracts to "ensur[e] that state law preserved [transit workers'] rights" and did not intend "to create a body of federal law" enforceable in federal court, *id.* at 27-28.

In *Empire HealthChoice*, this Court also acknowledged a cause of action to enforce a congressionally mandated contract, albeit under state law. That case

involved a health insurer's suit to enforce against an insured the reimbursement provision in its contract with the Office of Personnel Management. *See* 547 U.S. at 682, 683-85. Relying on *Jackson Transit*, the insurer and the United States argued that the insurer had a *federal* cause of action to enforce its federal contract. *See id.* at 693. The Court rejected that argument, holding that the claim arose under state law. The Court reasoned that the insurer's reimbursement right was found only in the contract, whereas the statute's "text itself contains no provision addressing the reimbursement . . . rights of carriers." *Id.* at 696-97. The four dissenting Justices, however, would have held that the insurer's claim "arises under federal common law" because the claim "concerns the application of terms in a federal contract." *Id.* at 706 (Breyer, J., dissenting).

In neither case, however, was there any dispute about *whether* the plaintiff had a cause of action to enforce the statutorily mandated contract; the only question was "the proper forum" for the claim. *Id.* at 682. Indeed, in *Jackson Transit*, the Court noted that the "union, *of course*, can pursue a contract action in state court," explaining that "it is reasonable to conclude that Congress expected the [statutory] agreement . . . , like [an] ordinary contract[], to be enforceable by private suit upon a breach." 457 U.S. at 20-21, 29 n.13 (emphasis added). The Court cited with approval *Local Division 732 v. Metropolitan Atlanta Rapid Transit Authority*, 667 F.2d 1327 (11th Cir. 1982), which similarly held that "there is no question but that there is a private cause of action for breach of [the] agreement," *id.* at 1333.

3. Thus, the issue presented in past cases was not *whether* the contract was enforceable, but *where*

Congress intended such contracts to be litigated — as *federal* causes of action or state-law claims.

Here, petitioners correctly concede that the Agreement "is a federal contract" and that § 256b "is the source of the contractual term allegedly breached." Br. 21, 42 & n.5. This case is thus squarely within *Central Airlines*, in which the Court held that Congress "intended the statutory command" to enter an "agreement" to "be legally enforceable" through a breach-of-contract action in federal court. 372 U.S. at 690; 45 U.S.C. § 184. As *Central Airlines* stressed, where Congress mandates creation of a contract and specifies the terms of certain provisions in that contract, such provisions are "governed and enforceable by federal law, in the federal courts." 372 U.S. at 692. Notably, petitioners neither cite nor discuss *Central Airlines*. Yet their discussion (at 21-25) of the Agreement's incorporation of the statutory command that manufacturers charge covered entities no more than the ceiling price (including by best-price calculations) pursuant to statutory standards confirms that the contract mandated by Congress creates federal rights enforceable in federal court.

Federal law also independently "controls the interpretation of the contract" because the United States "entered [the Agreement] pursuant to authority conferred by federal statute." *United States v. Seckinger*, 397 U.S. 203, 209-10 (1970); *see also Boyle v. United Techs. Corp.*, 487 U.S. 500, 504 (1988) ("[O[bligations to and rights of the United States under its contracts are governed exclusively by federal law."); *United States v. Allegheny County*, 322 U.S.

174, 183 (1944); *Clearfield Trust Co. v. United States*, 318 U.S. 363, 366 (1943).[43]

B. As Intended Third-Party Beneficiaries Of A Federal Contract, 340B Entities Have A Federal Cause Of Action To Enforce The Agreement

In selecting contracts as the means of implementing its determination that 340B entities should benefit by obtaining the same best prices available under Medicaid, Congress evinced no intent to depart from standard common-law contract principles, which include a cause of action in the event of a breach. *See Beck v. Prupis*, 529 U.S. 494, 500-01 (2000) (finding that Congress, in using a common-law concept, intended to adopt "'the cluster of ideas that were attached to each borrowed word in the body of learning from which it was taken and the meaning its use will convey to the judicial mind unless otherwise instructed. In such case, absence of contrary direction may be taken as satisfaction with widely accepted definitions, not as a departure from them.'") (quoting *Morissette v. United States*, 342 U.S. 246, 263 (1952)); *see also United States v. Wells*, 519 U.S. 482, 491 (1997); *Molzof v. United States*, 502 U.S. 301, 307 (1992); *NLRB v. Amax Coal Co.*, 453 U.S. 322, 329 (1981).

---

[43] In all events, as the Ninth Circuit held (*see* App. 8a-9a n.5), even if Santa Clara's breach-of-contract claim were a state-law claim, that claim still would arise under federal law under *Grable & Sons Metal Products, Inc. v. Darue Engineering & Mfg.*, 545 U.S. 308, 314 (2005). And, even if that claim were found not to arise under federal law, it would be enforceable in state court, as were the contracts at issue in *Empire HealthChoice* and *Jackson Transit*. *See supra* pp. 27-28.

1. A bedrock principle of the common law of contracts — dating back to English cases sounding in *assumpsit* — is that a class of third parties (now known as intended third-party beneficiaries) can sue to enforce contracts. *See Starkey v. Mill*, 82 Eng. Rep. 723 (K.B. 1651); *Dutton v. Poole*, 83 Eng. Rep. 523 (K.B. 1677). Following that English precedent, courts in this country long have held that, "where one person makes a promise to another for the benefit of a third person, that third person may maintain an action on such promise." *Schemerhorn v. Vanderheyden*, 1 Johns. 139, 140 (N.Y. Sup. Ct. 1806) ("The same principle has, since [*Dutton*], been repeatedly sanctioned by the decisions of the *English* courts."); *see also*, *e.g.*, *German Alliance Ins. Co. v. Home Water Supply Co.*, 226 U.S. 220, 230 (1912) (third party may enforce contract "intended for his direct benefit"); *Robins Dry Dock & Repair Co. v. Flint*, 275 U.S. 303, 307 (1927) (same); *United States ex rel. Johnson v. Morley Constr. Co.*, 98 F.2d 781, 788-89 (2d Cir. 1938) (L. Hand, J.); *Crumady v. The Joachim Hendrik Fisser*, 358 U.S. 423, 428 (1959); *Arthur Andersen LLP v. Carlisle*, 129 S. Ct. 1896, 1902 n.6 (2009) (noting "contract law's longstanding endorsement of third-party enforcement"); Melvin Aron Eisenberg, *Third-Party Beneficiaries*, 92 Colum. L. Rev. 1358, 1360-89 (1992) (discussing history).

Under modern doctrine, a third party is an intended (as opposed to incidental) beneficiary when "recognition of a right to performance in the beneficiary is appropriate to effectuate the intention of the parties and . . . the circumstances indicate that the promisee intends to give the beneficiary the benefit of the promised performance." Restatement § 302(1)(b).

Accordingly, an "intended beneficiary may enforce the duty." *Id.* § 304.

The same rule applies to a government contract, "except to the extent that application would contravene the policy of the law authorizing the contract or prescribing remedies for its breach." *Id.* § 313(1); *see Mobil Oil*, 530 U.S. at 608 (applying Restatement to interpret federal government contract); *Miree v. DeKalb County*, 433 U.S. 25, 32 (1977) (acknowledging state-law third-party beneficiary claim on contract between Federal Aviation Administration and municipality); *Audio Odyssey, Ltd. v. United States*, 255 F.3d 512, 520-22 (8th Cir. 2001) (holding small-business borrower was intended third-party beneficiary of loan guarantee agreement between lender and Small Business Administration); *Holbrook v. Pitt*, 643 F.2d 1261, 1269-73 (7th Cir. 1981) (holding tenants were intended third-party beneficiaries of contracts between developers of low-income housing and Department of Housing and Urban Development).

Where a third party does not seek consequential damages but only general damages — as here, where respondent seeks only reimbursement for manufacturers' overcharges in breach of their contractual promises — courts generally uphold the third party's rights as an intended beneficiary entitled to sue. *See* 3 E. Allan Farnsworth, *Contracts* 688-89 (3d ed. 1999) (where "consequential damages are not involved, so that the promisor's risk is more limited, . . . courts have permitted enforcement [of government contracts] by third persons"); Restatement § 313 cmt. a.

2. As both courts found below, 340B entities are intended third-party beneficiaries of the provision in the Agreement mandating that manufacturers

charge 340B entities prices that do not exceed the same best prices that States receive through Medicaid rebates. *See supra* pp. 15-17. Petitioners no longer dispute that 340B entities are, as a matter of contract law, intended third-party beneficiaries of the Agreement, having waived that issue in their certiorari petition, *see* Br. in Opp. 31-33, and failing to argue it in their merits brief.

The Agreement requires manufacturers "to charge covered entities a price . . . that does not exceed" the ceiling price. Agreement § II(a). Because 340B entities are specifically named in the Agreement, and because manufacturers have contracted to charge them no more than the ceiling price, 340B entities are intended third-party beneficiaries entitled to enforce that promise. *See*, *e.g.*, Restatement §§ 302(1)(b), 304.

Moreover, 340B entities' status as intended third-party beneficiaries can be traced directly to judgments of Congress, which expressly required an "agreement" containing a provision limiting "the amount required to be paid . . . by a covered entity" to an amount that "does not exceed" the ceiling price. § 256b(a)(1). Congress also described the Agreement as one "between the [340B] entity and the manufacturer." § 256b(a)(5)(D).

The legislative history accords with the unambiguous statutory text. Congress enacted § 256b, with its contract mechanism, specifically "to enable . . . certain Federally-funded clinics [*i.e.*, 340B entities] to obtain lower prices on the drugs that they provide to their patients" and "to enable these entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." 1992 House Report at 7,

12. As the court of appeals concluded, one is "unable to discern any substantial purpose of the [Agreement] *other* than to grant eligible covered entities a discount on covered drugs." App. 43a.

As the Ninth Circuit further determined, "the right to sue inheres in one's status as an intended beneficiary," because the right to sue is precisely what distinguishes intended from incidental beneficiaries. App. 39a (citing, *inter alia*, Restatement § 304 ("the intended beneficiary may enforce the duty")). There is no need to seek (as the district court mistakenly thought) additional indications that intended beneficiaries may enforce the ceiling price. *See Montana v. United States*, 124 F.3d 1269, 1273 (Fed. Cir. 1997) (rejecting such a requirement).

3. Finally, until recently, § 256b contained no statutory administrative remedy that arguably could displace the standard common-law breach-of-contract remedy available to intended third-party beneficiaries. As this Court has stressed specifically in the context of federal common-law remedies, when Congress seeks "to abrogate a common-law [remedial] principle, the statute *must speak directly* to the question addressed by the common law." *United States v. Texas*, 507 U.S. 529, 534 (1993) (emphasis added; internal quotations omitted) (Debt Collection Act of 1982 did not abrogate United States' federal common-law right to collect pre-judgment interest on debts owed to it by States); *see also Exxon Shipping Co. v. Baker*, 128 S. Ct. 2605, 2619 (2008) (Clean Water Act did not displace federal common law of punitive damages, citing *Texas*); *Astoria Fed. Sav. & Loan Ass'n v. Solimino*, 501 U.S. 104, 108 (1991) ("[W]here a common-law principle is well established, . . . the courts may take it as given that Congress has legis-

lated with an expectation that the principle will apply except 'when a statutory purpose to the contrary is evident.'") (quoting *Isbrandtsen Co. v. Johnson*, 343 U.S. 779, 783 (1952)); *cf.* Restatement § 313. Applying this principle, the Court recently held that, because Congress did not "purport[] to alter background principles of state contract law" in the Federal Arbitration Act, a "third-party beneficiary" to a contract could seek a stay to enforce a contract's arbitration provision. *Arthur Andersen*, 129 S. Ct. at 1902 (internal quotations omitted).

In claiming that Congress meant for 340B entities to have no contract enforcement rights, the United States (at 30-31) relies on provisions in the Medicaid statute (enacted two years before § 256b) that provide for civil monetary penalties and termination from Medicaid as potential sanctions for manufacturers' failure to report accurate prices. *See also* Pet. Br. 38. Neither provision displaces a breach-of-contract remedy for 340B entities to enforce the Agreement. Indeed, the United States draws the wrong conclusion from Congress's silence on 340B entities' contract-enforcement rights. The applicable principle is that Congress must speak clearly when it intends to displace common-law remedies. *See Beck*, 529 U.S. at 501 ("'[A]bsence of contrary direction may be taken as satisfaction with widely accepted [common-law] definitions, not as a departure from them.'") (quoting *Morissette*, 342 U.S. at 263).

Furthermore, the only administrative procedure for 340B entities to recover overcharges was purely elective. *See* 2005 Deficiencies Report at 16-17. HHS made clear that "[c]overed entities or manufacturers are not required" to use the informal process. 61 Fed. Reg. at 65,411. HHS also acknowledged that

such "parties" may instead "resort[] to other remedies which may be available under applicable principles of law," which is what respondent has done here. *Id.* at 65,411-12.[44]

II. NEITHER PETITIONERS NOR THE UNITED STATES PROVIDE GROUNDS FOR IGNORING CONGRESS'S DECISION TO IMPLEMENT § 256B THROUGH ENFORCEABLE FEDERAL CONTRACTS

A. This Court's Private-Right-Of-Action Case Law Is Inapposite

1. As this Court has recognized, cases in which a party seeks to enforce provisions in a contract that Congress mandated to implement a statutory scheme "do[] not fit comfortably in th[e] mold" of "private right of action case[s]." *Jackson Transit*, 457 U.S. at 20. A plaintiff may "state[] a federal claim when he sue[s] to vindicate contractual rights set forth by federal statutes, *despite* the fact that the relevant statutes lacked express provisions creating federal causes of action." *Id.* at 22 (emphasis added).

Nonetheless, petitioners and their *amici* — except, notably, the United States — attempt to force this case into the implied private right of action mold. Petitioners and these *amici* offer no explanation for Congress's decision to implement § 256b through what petitioners recognize (at 42) are "federal contract[s]." Congress instead could have required manufacturers, as a condition on Medicaid coverage for their drugs, to charge 340B entities no more than

---

[44] The United States (at 31-32) contends that HHS did not there suggest that 340B entities (as opposed to manufacturers) were among the "parties" with "other remedies," but that is the only reasonable reading of "parties" in context.

the ceiling price, with the Secretary directed to promulgate regulations to implement that requirement. Under such a hypothetical statute, 340B entities would need a private right of action to enforce the statutory and regulatory obligations Congress and HHS imposed.

On petitioners' view, that hypothetical statute is no different from the one Congress actually enacted, which deprives of all meaning Congress's choice to require contracts and violates "one of the most basic interpretive canons, that a statute should be construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void or insignificant." *Corley v. United States*, 129 S. Ct. 1558, 1566 (2009) (internal quotations and alteration omitted); *see also Bennett v. Spear*, 520 U.S. 154, 173 (1997).[45]

Petitioners' invocation of the Court's implied-right-of-action cases is thus entirely misplaced. That is true in particular of *Alexander v. Sandoval*, 532 U.S. 275 (2001), which considered whether "language in a regulation can conjure up a private cause of action that has not been authorized by Congress." *Id.* at 291; *see id.* at 292 (noting that the regulations at issue went "beyond the statutory prescription of [42 U.S.C. § 2000d]"). Here, in contrast, *Congress* mandated the creation of enforceable contracts that would include a provision providing a benefit directly to 340B entities.

---

[45] Petitioners' reliance (at 20-21) on cases arising under the Spending Clause similarly ignores Congress's choice to implement section 340B through actual contracts, rather than a Spending Clause mandate that is simply "in the nature of a contract." *Barnes v. Gorman*, 536 U.S. 181, 186 (2002) (internal quotations and emphasis omitted).

Equally flawed is petitioners' passing attempt (at 44) to distinguish *Jackson Transit* and cases in which this Court has recognized the existence of a federal cause of action to enforce federal contracts as raising only "a choice of law question." Petitioners ignore the Court's crucial antecedent recognition that Congress necessarily intends for contracts to be *enforceable*, regardless of whether a breach-of-contract claim is a federal- or state-law cause of action. *See Jackson Transit*, 457 U.S. at 29 n.13 (explaining that the "union, *of course*, can pursue a contract action," albeit there "in state court") (emphasis added).

Petitioners also erroneously claim (at 28-32) that a right to sue to enforce the ceiling price provision in the Agreement is no different from a private right of action to enforce § 256b. If 340B entities had a private right of action, they could enforce not only the terms of the Agreement, but also manufacturers' obligation to sign an Agreement in order to maintain coverage for their drugs under Medicaid. *See* §§ 256b(a), 1396r-8(a)(1), (5)(A). Lacking that private right of action, 340B entities cannot compel a manufacturer to sign an Agreement or recover discounts from a manufacturer that was required, but refused, to sign an Agreement. That difference is significant. When respondent filed suit, a number of manufacturers benefiting from Medicaid coverage for their drugs still had not complied with their statutory duty to execute an Agreement.[46]

---

[46] *See 2006 Oversight Hearing* at 46 (prepared statement of William H. von Oehsen, III, General Counsel, Public Hospital Pharmacy Coalition) ("[T]here are a number of manufacturers that have avoided or delayed entering into [a] 340B [Agreement] notwithstanding the continued coverage of their products by Medicaid.").

2. Petitioners claim (at 26-28) that two cases support precluding 340B entities from bringing a breach-of-contract claim to enforce the Agreement. Neither supports them.

Universities Research Association, Inc. v. Coutu, 450 U.S. 754 (1981), was *not* a breach-of-contract case. Instead, the plaintiff claimed a violation of the Davis-Bacon Act: namely, that the contract under which he was paid should have contained provisions requiring that he be paid the prevailing wage. Because the contract "does not contain a prevailing wage stipulation," the only question before the Court was whether the plaintiff had an implied private right of action under the Davis-Bacon Act. *Id.* at 756. The Court found that he did not. *See id.* at 771-784.

The Court, however, left open questions about the enforcement of a contract containing Davis-Bacon provisions and expressly noted the petitioners' concession at oral argument that an employee may have a state-law claim to enforce such a contract as an intended third-party beneficiary. *See id.* at 769 n.19. The United States, in its *amicus* brief in *Coutu*, had gone further and argued that "[t]here is no need for the Court to decide in this case whether such a private right of action may be implied in favor of an employee under a contract that *contains* Davis-Bacon stipulations," because an employee claiming a breach of that contract "should be able to recover in a suit on the contract as a third-party beneficiary." U.S. Amicus Br. at 17 n.14, *Universities Research Ass'n,*

Inc. v. Coutu, No. 78-1945 (U.S. filed June 1980); *see id.* at 22 (same).[47]

Equally inapposite is *United States v. Erika, Inc.*, 456 U.S. 201 (1982). There, the Court found that Congress had precluded judicial review of Medicare Part B payment decisions. *See id.* at 206. The Court rejected the respondent's claim that it could sue "as a third-party beneficiary to [the insurer's] contract with the United States," explaining that "any such contract[] . . . necessarily would include the statutory preclusion of [judicial] review." *Id.* at 211 n.14.[48] Neither § 256b nor the Agreement contains any comparable provision that could preclude 340B entities from enforcing their rights as intended third-party beneficiaries to recover drug manufacturer overcharges.

3. Congress's decision to implement § 256b through federal contracts, against well-settled background principles that provide a cause of action for intended third-party beneficiaries, provides all the evidence of congressional intent necessary and must be respected. The Ninth Circuit's holding that 340B entities are intended third-party beneficiaries of the Agreement thus reflects neither "judicial creativity" nor "turn[ing] back the clock" on this Court's private-

---

[47] Subsequently, some courts have found no right to enforce Davis-Bacon Act contracts as third-party beneficiaries on the ground that a binding administrative dispute resolution scheme — which is absent here — precludes such claims. *See*, *e.g.*, *Grochowski v. Phoenix Constr.*, 318 F.3d 80, 85-86 (2d Cir. 2003) (cited at Pet. Br. 29).

[48] *See also Hodges v. Atchison, T. & S.F. Ry. Co.*, 728 F.2d 414, 416 (10th Cir. 1984) (finding third-party beneficiary claim precluded by "the comprehensive remedial scheme provided in the [Rehabilitation Act of 1973]").

right-of-action precedents (PhRMA Br. 9, 11), but rather enforcement of contracts *expressly required by Congress*, under long-settled principles in this Court and under the common law of contracts.

Certainly Congress may, by positive statutory enactment, establish administrative remedies that displace federal common-law remedies. *See*, *e.g.*, *Firestone Tire & Rubber Co. v. Bruch*, 489 U.S. 101, 108 (1989). Unlike petitioners and their other *amici*, the United States argues (at 12-14) that the PPACA contains a new directive for HRSA to create an administrative process to resolve claims of overcharges, which the United States contends will preclude future breach-of-contract suits by 340B entities. Whether that process, once implemented,[49] will preclude future breach-of-contract claims is not presented here, as respondent's claims well precede the PPACA's enactment. Indeed, the United States concedes (at 12, 14) that this process "will not apply to the claims at issue in this case," as the statute applies only "to drugs purchased on or after January 1, 2010."[50]

B. The United States' Novel Assertions Are Both Unsupported And Outside The Question Presented

The United States is unwilling to defend petitioners' reliance on the Court's implied-right-of-action case law. Instead, the United States advances erro-

---

[49] HHS failed to meet Congress's deadline to promulgate regulations by September 19, 2010. *See supra* note 16.

[50] If the United States is correct that the remedy HHS creates for sales from January 1, 2010, forward through its new statutory authority is exclusive, it severely limits the importance of the Question Presented and arguably warrants dismissal of the certiorari petition as improvidently granted.

neous arguments not fairly included in the Question Presented or advocated by petitioners. *See Yee v. City of Escondido*, 503 U.S. 519, 535 (1992) ("[W]e ordinarily do not consider questions outside those presented in the petition for certiorari."); *Kamen v. Kemper Fin. Servs., Inc.*, 500 U.S. 90, 97 n.4 (1991) (declining to address issue raised solely by Solicitor General "because we do not ordinarily address issues raised only by *amici*"); Sup. Ct. R. 14.1(a).

1. The United States' artificial distinction between "regulatory" contracts and "ordinary" contracts fails

a. Section 256b(a)(1) requires that "[t]he Secretary shall enter into an agreement with each manufacturer of covered outpatient drugs" to charge no more than the ceiling price. The Secretary implemented that directive by creating the Agreement. Petitioners, all of which signed an Agreement, recognize that the Agreement "is a federal contract," Br. 42; *see id.* at i (Agreement is "the contract"), as does the drug manufacturers' association, *see* PhRMA Br. 2, 9 ("contract"). The parties also agreed before the Ninth Circuit that the Agreement is a contract, and the United States nowhere disputed that fact, instead describing the Agreement as a "government contract" or "340B contract," U.S. C.A. Amicus Br. 12, 18, 26-27.

Now, however, the United States contends (at 15) that the Agreement is not any kind of a contract at all, but is, in effect, no different from an agency regulation because it "does not give rise to any enforceable contractual rights in manufacturers or in covered entities as third-party beneficiaries." That novel effort is an implicit concession that, *if* the Agreement is a federal contract (and if 340B entities are intended

third-party beneficiaries, another question that only the United States disputes), 340B entities have a federal cause of action.

b. The United States' attempt to deny that the Agreement is a contract fails. As the United States acknowledges (at 15), § 256b "is structured as an opt-in program in which drug manufacturers may voluntarily choose to participate." Although manufacturers have an obligation to enter an Agreement if they sell their drugs as part of the Medicaid program, the obligation to charge the ceiling price attaches only when the manufacturer signs the Agreement and not before. That feature further evidences that the Agreement is a contract. *See United States v. Bloom*, 112 F.3d 200, 204 (5th Cir. 1997) ("The statute [permitting academic scholarship awards] . . . does not of its own force subject the parties to [the statutory] conditions . . . . Not until the agreement is signed do the parties assume any responsibilities.").

The United States' position also conflicts with the origin of the statutory scheme. When Congress enacted the Medicaid Rebate Program, it allowed pre-existing contracts between manufacturers and state Medicaid programs to substitute for the statutory agreements so long as they provided equivalent benefits, evidencing Congress's understanding that the new rebate agreements were to be enforceable contracts no less than the existing ones. *See* § 1396r-8(a)(4); *supra* note 8. Two years later, Congress extended that same contracting regime to the 340B program.

c. The United States nonetheless claims (at 15) that the Agreement is "statutory and regulatory — not contractual — in nature" and thus unenforceable by "manufacturers or . . . covered entities." In

Winstar, however, a four-Justice plurality squarely rejected a similar argument, ruling that contracts applying regulatory policy are nevertheless enforceable. "[A]llowing the Government to avoid contractual liability merely by passing any 'regulatory statute' would flout the general principle that, '[w]hen the United States enters into contract relations, its rights and duties therein are governed generally by the law applicable to contracts between private individuals.'" 518 U.S. at 895 (plurality) (quoting *Lynch v. United States*, 292 U.S. 571, 579 (1934)) (finding that contracts between bank regulators and banks acquiring distressed thrifts were breached when Congress by statute changed the capital requirements on which the agreements were based, making the United States liable in damages) (second alteration in original). The plurality further noted that an exception for government "contracts that are 'regulatory' in nature . . . would raise enormous analytical difficulties" because "the Government may wish to further its regulatory goals through contract." *Id.* at 886.[51]

The cases the United States cites (at 14-21) suggest only that some contract-law principles apply differently to contracts that implement federal statutes. But none suggests that breach-of-contract remedies do not exist for such contracts. Thus, in *Bennett v. Kentucky Department of Education*, 470 U.S. 656 (1985), this Court *enforced* a federal grant agreement, declining only to rule "that ambiguities . . . should invariably be resolved against the Federal Government as the drafter of the grant agreement." *Id.* at 669. In *Bowen v. Public Agencies Opposed to*

[51] The three Justices concurring in the judgment raised no objection to that analysis.

Social Security Entrapment, 477 U.S. 41 (1986), the Court held that a statutory agreement between federal and state governments necessarily incorporated Congress's statutory reservation of rights to amend the Social Security Act and thus did not create vested Fifth Amendment property rights. *Id.* at 54. In other cases, this Court found merely that there was no government contract — not that any such contract was unenforceable. *See Flemming v. Nestor*, 363 U.S. 603, 610 (1960) (employees have only a "noncontractual interest" in Social Security benefits); *United States R.R. Retirement Bd. v. Fritz*, 449 U.S. 166, 174 (1980) ("[R]ailroad benefits, like social security benefits, are not contractual and may be altered or even eliminated at any time."); *National R.R. Passenger Corp. v. Atchison, T. & S.F. Ry. Co.*, 470 U.S. 451, 465 (1985) (railroads' contracts with Amtrak, a private corporation, were not with the United States).[52]

Among lower-court cases, the United States (at 17, 18, 20) relies primarily on *Rendleman v. Bowen*, 860 F.2d 1537 (9th Cir. 1988), which held only that, in interpreting statutory contracts between the Government and scholarship recipients, "[s]tatutory intent . . . is more relevant to the interpretation of these conditions." *Id.* at 1541 (enforcing contract).[53] And the same court subsequently "reject[ed] the government's understanding of the [statutory] scholar-

---

[52] *See also Hollander v. Brezenoff*, 787 F.2d 834, 838 (2d Cir. 1986) ("appellant does not claim that any specific obligation undertaken in [government] agreements was breached") (cited at U.S. Br. 20).

[53] *See also American Hosp. Ass'n v. Schweiker*, 721 F.2d 170, 183 (7th Cir. 1983) (contractual "scope and interpretation" was a question "more of statutory construction than of contract law") (cited at U.S. Br. 17, 20).

ship agreement [at issue in *Rendleman*] as noncontractual," because "Congress described the agreement between the scholarship recipient and government as a 'contract'" in the relevant statute. *United States v. Westerband-Garcia*, 35 F.3d 418, 420 (9th Cir. 1994) (applying federal statute of limitations for contracts). Moreover, contrary to the United States' suggestion (at 18), "[t]he fact that the parties do not bargain for the terms of the agreement, but must take the terms as set forth in [the statute], does not mean that the agreement is not a contract." 35 F.3d at 421. Under the United States' rationale, no consumer's assent to a corporation-drafted form agreement would ever be deemed a "contract." *But see* Restatement § 211 (assent to "[s]tandardized [a]greement[]" creates legally enforceable contract).

In all events, to conclude that statutory provisions incorporated in government contracts bear on "the parties' likely intent . . . *is to apply, not to disregard*, the ordinary rule of contract law." *Winstar*, 518 U.S. at 913 (Breyer, J., concurring) (emphasis added). Moreover, Congress's ability to alter the Agreement's terms legislatively is not germane to whether the existing terms are contractually enforceable. *See* U.S. Br. 19-21. It shows only that manufacturers agreed in the Agreement that referenced statutory definitions would apply as Congress might amend them from time to time. *See, e.g.*, Agreement § I(b) ("'*Best Price*' has the meaning given it in [§ 1396(c)(1)(C)]").

d. Finally, the United States attempts to draw support for its claim that the Agreement is not enforceable through a breach-of-contract suit by pointing to Congress's recent enactment of the PPACA, which it suggests "demonstrates that Congress regards the 340B Program as essentially statutory and

regulatory — not contractual — in nature." U.S. Br. 14, *see id.* at 33. This Court often has held that later enactments are "'beside the point'" in construing prior ones. *Gutierrez v. Ada*, 528 U.S. 250, 258 (2000) (quoting *Almendarez-Torres v. United States*, 523 U.S. 224, 237 (1998)). The new provisions designed to ensure 340B program integrity are, however, congressional confirmation that HRSA was not fulfilling the statute's goal of ensuring that 340B entities get the best prices available in the marketplace. That later enactment thus may imply that Congress perceived existing contract actions to enforce manufacturers' obligations in the Agreement to be insufficient, but it says nothing about whether § 256b properly is construed to create contracts enforceable through third-party beneficiary claims. Instead, under this Court's decisions, Congress's use of contracts requires that they be treated as such when manufacturers breach the Agreement.

2. 340B entities are intended third-party beneficiaries of the Agreement

Despite petitioners' waiver of the claim, *see supra* p. 33, the United States disputes that 340B entities are intended third-party beneficiaries entitled to enforce manufacturers' promise to charge no more than the ceiling price. But in contending that the Secretary did not intend for the Agreement to create such third-party rights, the United States asks (at 25-27) the wrong question. It was Congress that required the Secretary to draft a contract that included a provision specifically intended to benefit 340B entities. The Secretary had no discretion to exclude that provision from the Agreement or to preclude any third-party beneficiary rights that flow from that provision. Moreover, the United States' claim conflicts

with Congress's description of the Agreement as one "between the [340B] entity and the manufacturer." § 256b(a)(5)(D).[54]

The United States, however, claims (at 26-27) that the Agreement provision permitting the Secretary or a manufacturer, but not a covered entity, to initiate the Agreement's voluntary dispute resolution process indicates that the Secretary did not intend to confer third-party beneficiary rights on covered entities. Again, the United States asks the wrong question, because *Congress's* intent controls here, as reflected in the provisions of the Agreement that Congress mandated, not the Secretary's subjective intent. In any case, there is no asymmetry in the elective dispute resolution process, because the Secretary has a separate elective procedure that covered entities can use. *See* U.S. Br. 26-27 (citing 61 Fed. Reg. at 65,412).

Nor is it significant that 340B entities typically buy their supplies from wholesalers and thus lack "privity" with the manufacturer. U.S. Br. 27-28. Congress expressly provided in the statute for such wholesale arrangements and, at the same time, required manufacturers to charge 340B "covered entit[ies]" an amount that "does not exceed" the ceiling price. § 256b(a)(1); *see* § 256b(a)(8) ("Secretary shall establish a prime vendor program" for "distribution of cov-

---

[54] The United States similarly asks the wrong question in claiming (at 28-29) that the statutory confidentiality provision precluded the Secretary from deciding to confer intended third-party beneficiary status on 340B entities. In any event, as explained below, the United States' reliance on the confidentiality provision lacks merit. *See infra* pp. 52-53.

ered outpatient drugs").[55] Thus, the statutory text plainly expresses Congress's intent to benefit 340B entities, irrespective of privity with manufacturers.

III. ACTIONS BY 340B ENTITIES TO REMEDY DRUG MANUFACTURER OVERCHARGES ARE CONSISTENT WITH FEDERAL ENFORCEMENT EFFORTS AND SOUND POLICY

A. Congress Did Not Intend For Exclusive Federal Enforcement Of The Agreement's Ceiling-Price Provision

Enforcement of the Agreement by 340B entities complements, without interfering in, federal enforcement efforts.

1. Respondent seeks to enforce the ceiling-price provision of the Agreement; it does not seek to impose additional or different obligations on manufacturers. The United States previously recognized that principle in an *amicus* brief authorized by the Solicitor General in the context of a State's allegations that a manufacturer had concealed its actual best prices:

> [Where] a state sues a drug manufacturer that failed to calculate its best price obligations in accordance with the rebate agreement or CMS guidance — but does *not* seek to impose any additional or contrary obligations — the state is merely enforcing the existing rebate program responsibilities and does not inject any more var-

---

[55] *See also* 2006 Overcharge Report at 2 ("If a manufacturer's drugs are available to entities through wholesalers, the 340B discount must be made available through that avenue.") (citing 59 Fed. Reg. 25,110, 25,113 (May 13, 1994) ("A covered entity is permitted to use a purchasing agent without forfeiting its right to the section 340B drug discounts.")).

> iation [in the national Medicaid regime] than if the Department of Justice brought suit.

U.S. *Mass.* Amicus Br. 17 (emphasis added); *see also* U.S. Br. 34 n.14 (citing same brief).

Relying on that *amicus* brief, the Massachusetts district court later held (in a separate case) that States can sue drug manufacturers to enforce the best-price and other requirements of the Medicaid rebate agreement as a "third-party intended beneficiary," despite the absence of a private right of action in that statute. *Massachusetts v. Mylan Labs.*, 357 F. Supp. 2d 314, 329 (D. Mass. 2005) (citing U.S. *Mass.* Amicus Br. 17). The court found that allowing States to sue as intended third-party beneficiaries was "consistent with the statutory scheme, and not an end-run on it." *Id.* at 328.

2. The United States also has made clear that courts are well-suited to adjudicate claims, like respondent's here, that manufacturers improperly have excluded bundled discounts in calculating the best prices of their brand-name drugs. In the pending FCA case against Wyeth, the United States successfully defended against Wyeth's motion to dismiss — in which Wyeth raised arguments similar to those in petitioners' brief here[56] — by arguing that "[w]hether transactions under [Wyeth's contracts] constitute 'bundled sales' is ultimately a matter for judicial interpretation, and it is Wyeth's compliance with those requirements, as interpreted by the Court, that determines whether it submitted false Best Price reports." U.S. Opp. to Motion To Dismiss at 37, *United States ex rel. Kieff v. Wyeth*, Nos. 03-

---

[56] *Compare* Wyeth Motion To Dismiss at 31-39, *United States ex rel. Kieff v. Wyeth*, Nos. 03-CV-12366-DPW & 06-CV-11724-DPW (D. Mass. filed Nov. 6, 2009), *with* Pet. Br. 33-37.

CV-12366-DPW & 06-CV-11724-DPW (D. Mass. filed Dec. 11, 2009) ("U.S. *Wyeth* MTD Opp."); *see id.* at 38 (explaining that Wyeth's reported best prices are "objectively false" if, "as the government contends," Wyeth improperly excluded bundled discounts from its best-price calculations).

Indeed, the United States rejected Wyeth's contention — which is identical to petitioners' assertion here (at 33-34) — that regulatory ambiguities render best-price calculations inherently too complex for such objective determinations. The United States argued that any complexity is "not an excuse for Wyeth to ignore the Rebate Agreement" and expressly endorsed the Ninth Circuit's ruling below in this case, which had "specifically rejected the argument by Wyeth (and other manufacturers) that the Rebate Agreement was in all cases too complex for a court to enforce without first referring the matter to the Secretary." U.S. *Wyeth* MTD Opp. 40 n.18; *see also Bates*, 544 U.S. at 452 ("While it is true that properly instructed juries might on occasion reach contrary conclusions on a similar issue of misbranding, there is no reason to think such occurrences would be frequent or that they would result in difficulties beyond those regularly experienced by manufacturers of other products that every day bear the risk of conflicting jury verdicts."). To the extent difficult issues arise, they can be dealt with through primary jurisdiction referrals. But many disputes will not implicate the agency's expertise, as the United States made clear below, because "it could turn out that any overcharging resulted from . . . obvious and intentional fraud that does not implicate the agency's interpretative expertise." U.S. C.A. Amicus Br. 25.

Court decisions to make such primary jurisdiction referrals on a "case-by-case" basis (U.S. Br. 35 n.15) are perfectly consistent with the United States' position in the Ninth Circuit, urging that a decision on a primary jurisdiction referral await further factual development. *See* U.S. C.A. Amicus Br. 22. The United States' claim (at 35 n.15) that such referrals "could interfere with HHS's enforcement priorities" is overstated, because a primary jurisdiction referral is equivalent to a request for a declaratory ruling, which private parties are permitted to file without regard to the agency's "enforcement priorities."

A court's capability to determine whether manufacturers violated their duties under the Agreement is no different whether a case begins with a private whistleblower complaint under the FCA, a State's complaint under state law or for breach of the Medicaid rebate agreement, or a 340B entity's breach-of-contract complaint. The United States is mistaken (at 34 n.14) that suits by 340B entities are "quite different from suits by States" because "the United States would play a cooperative role" and thereby prevent "inconsistent judgments uninformed by HHS's expertise." Nothing *requires* the United States to join in a State's lawsuit or a private FCA case. *See Vermont Agency of Natural Res. v. United States ex rel. Stevens*, 529 U.S. 765, 770 (2000) (relator may pursue FCA claims alone if United States declines to do so). And nothing *precludes* the United States from intervening or participating as an *amicus* in a case brought by a 340B entity.

Thus, as this Court has found is true in other contexts, "[p]rivate remedies that enforce federal [statutory] requirements would seem to aid, rather than hinder, the functioning of [the statute]." *Bates*,

544 U.S. at 451; *see also Wyeth v. Levine*, 129 S. Ct. 1187, 1202 (2009) (rejecting federal preemption of state-law failure-to-warn claims where "[t]he FDA has limited resources to monitor the 11,000 drugs on the market, and manufacturers have superior access to information about their drugs") (footnote omitted); *id.* at 1203 n.12 (private suits "'can serve as a catalyst'" to identifying unlawful acts) (quoting *Bates*, 544 U.S. at 451).

Petitioners and the United States, however, assert that the confidentiality provision in the Medicaid rebate statute (§ 1396r-8(b)) precludes 340B entities from obtaining the discovery necessary to identify a manufacturer's failure to calculate best prices and AMPs in accordance with the terms of the Agreement. *See* Pet. Br. 40; U.S. Br. 28-29. However, the data that respondent needs to show a violation of the ceiling-price provision are (a) the prices it paid, which respondent knows, and (b) the manufacturers' actual best price, which is determined using materials never provided to the federal government. The confidentiality provision covers neither set of data.

Moreover, the confidentiality provision has no application to court litigation. As the United States has explained, § 1396r-8(b) "does not preclude" a plaintiff from obtaining data necessary to identify a failure to calculate AMP or best price in accordance with the terms of the Agreement "from other sources (such as Defendants)." U.S. *Mass.* Amicus Br. 15; *see also* App. 20a-21a (rejecting petitioners' claim that confidentiality provision precludes production pursuant to "discovery order" and noting that "courts routinely enter protective orders to prevent the undue disclosure of commercially sensitive information").

3. The United States has concluded elsewhere that "it is unreasonable to infer that the Secretary should bear the sole responsibility for monitoring best price fraud." U.S. *Mass*. Amicus Br. 14. As the United States there explained, the Medicaid "rebate statute [§ 1396r-8] does not contain any provision . . . that would suggest a Congressional desire for exclusive federal enforcement." *Id.* at 13-14. The United States further stressed that the Medicaid "drug rebate scheme . . . is not specifically designed for identifying fraud." *Id.* at 14. Thus, "neither the rebate statute nor rebate agreement provides for the periodic or systematic review [by CMS] of manufacturer best price calculations or methodologies." *Id.* Moreover, the "rebate program does not require manufacturers to submit invoices to support their best price calculations or to regularly explain their methodologies for calculating AMP or best price." *Id.*; *see In re Pharm. Indus. Average Wholesale Price Litig.*, 321 F. Supp. 2d 187, 199 (D. Mass. 2004) (noting that "the Secretary does not make an independent determination with respect to Best Price"). The United States' *amicus* brief below likewise acknowledged that "[m]anufacturers normally do not report the data or reasoning underlying their AMP and Best Price calculations." U.S. C.A. Amicus Br. 4.

Accordingly, the United States' description (at 30) of the Medicaid statute as containing a "comprehensive remedial scheme that enables HHS to ensure that manufacturers accurately calculate and report AMP and Best Price," and its related claim (at 32-33) that "Congress centralized enforcement in the [federal] government," are squarely at odds with its previous — and correct — positions on those issues in the Massachusetts case. *See also* Pet. Br. 32-33

(similarly asserting that Congress enacted "comprehensive" administrative enforcement regime). The Solicitor General, which approved the United States' *amicus* submission in the Massachusetts case, offers no reason here based in any change in law for the United States' change of position.

The United States' earlier court submission that the Secretary is not the exclusive enforcer of manufacturers' obligations with respect to AMPs and best prices applies with even greater force in the context of § 256b. Nothing in the Agreement (or § 256b) requires manufacturers to submit to HRSA the documents and data necessary to verify the best and average manufacturer prices reported to CMS, which HRSA uses to calculate the ceiling price under the Agreement. Nor does (pre-PPACA) § 256b contain any provision suggesting exclusive enforcement by the Secretary. Indeed, only in 2010 — 18 years into the program — did HRSA first receive statutory authority "to verify the accuracy of ceiling prices." § 256b(d)(1)(B)(i).

B. Actions By 340B Entities To Enforce The Agreement Are Necessary In Light Of The Near-Complete Absence Of Federal Enforcement To Remedy Manufacturer Overcharges

Although petitioners and the United States repeatedly identify actions that HHS "may" take to remedy manufacturer overcharges, Pet. Br. 38-39; U.S. Br. 4-5, they are notably silent about actions HHS *has* taken, despite a steady stream of government reports and whistleblower suits revealing extensive over-

charging by manufacturers.[57] In fact, HHS enforcement has been almost non-existent and has been patently insufficient to protect 340B entities.

Although manufacturers are required to report their best prices and AMPs to the Secretary (via CMS), *see* § 1396r-8(b)(3)(A), they are not required to provide documents and analyses supporting those reported prices — much less documents that would reveal a manufacturer's improper exclusion from its reported best prices of bundled discounts, kickbacks, lick-and-stick sales, or other schemes. *See* U.S. *Mass.* Amicus Br. 14. As GAO explained, CMS "does not generally review the methods and underlying assumptions that manufacturers use to determine best price and AMP" and "does not verify that such documentation is kept and rarely requests it." 2005 Inadequate Oversight Report at 11. Even where "OIG found problems with manufacturers' price determination methods and reported prices . . . , CMS has *not* followed up with manufacturers to make sure that the identified problems with prices and price determination methods have been resolved." *Id.* at 10 (emphasis added).

Because CMS does not verify manufacturers' reported best prices and AMPs, the 340B ceiling prices calculated using those reported prices likewise are not verified. HRSA also "does not conduct audits or spot checks" of the prices 340B entities actually pay

---

[57] Although the Medicaid statute provides authority for the Secretary to terminate either an Agreement or a Medicaid rebate agreement, *see* § 1396r-8(b)(4)(B)(v), OIG has concluded that this is an "extremely severe sanction" that has the counterproductive effect of limiting "access to medications for the millions of Medicaid and 340B beneficiaries." 2005 Deficiencies Report at 16.

and so is "unable to detect whether . . . entities are paying" more than the ceiling prices calculated using the unverified figures reported to CMS. 2005 Deficiencies Report at 15, 16. Neither agency has the staff or budget to engage in meaningful reviews of drug manufacturers' reported AMPs and best prices for the more than 35,000 drugs (*see* Pet. Br. 34) that Medicaid and 340B entities purchase. *See* 2010 Noncompliance Report at 14.[58] In sum, the agency undertakes virtually no investigation and enforcement of the veracity of the best-price and AMP figures manufacturers use to calculate the 340B ceiling prices (or, for that matter, of the figures used to calculate state Medicaid rebates).

The only enforcement alternative to intended third-party beneficiary suits for sales to 340B entities (prior to full implementation of the PPACA) is whistleblower suits under the FCA, on which the United States and petitioners' trade association — but not petitioners themselves — rely. *See* U.S. Br. 30-31; PhRMA Br. 14-15. But hoping that insider whistleblowers will come forward with evidence of best-price violations and be able to navigate the intricate jurisdictional requirements of a successful FCA suit is hardly a sensible primary enforcement

---

[58] The United States' claim that "HRSA has implemented many improvements in response" to the highly critical OIG reports is wholly unsubstantiated. *See* U.S. Br. 32 n.13 (citing 2005 Deficiencies Report at 9-10, 12 (criticizing HHS's best-price and AMP "pricing data" and "general lack of detailed procedures for calculating the 340B ceiling price" as being "of little use to the agency's oversight of the 340B Program")). It is, moreover, contradicted by Congress's judgment in the PPACA that HHS — at long last — must "develop[] . . . a system to enable the Secretary to verify the accuracy of ceiling prices calculated by manufacturers." § 256b(d)(1)(B)(i).

mechanism for such an important government program. Notably, the United States cites no authority suggesting that the FCA displaces longstanding and pre-existing common-law remedies for breach of contract. Moreover, FCA cases require a showing that the violation was made "knowingly" and allow for treble damages and fines in appropriate cases. 31 U.S.C. § 3729(a)(1), (2). Third-party breach-of-contract actions, in contrast, have no scienter requirement and seek only general damages (that is, a refund of the amounts overcharged), and thus focus more directly and comprehensively on the harm that 340B entities suffer when manufacturers breach the Agreement and charge more than the ceiling price for their drugs.

Petitioners assert (at 40-41) that 340B entities and States have differing interests in combating manufacturer misreporting of the AMP with respect to drugs where the best price does not determine the ceiling price.[59] Although it suggested similarly in the court below, the United States no longer advances that contention. In this Court, petitioners offer no claim that manipulating average prices is materially profitable to manufacturers or that the supposed conflict between States and 340B entities in this regard is anything other than hypothetical. In contrast, best-price manipulation can be highly lucrative for petitioner drug manufacturers; the whistleblower cases and government reports *all* concerned best-price manipulation. *See supra* pp. 8-11.

As petitioners acknowledge (at 41), the interests of 340B entities and States are perfectly aligned

---

[59] For some brand-name drugs, the ceiling price is AMP minus 15.1%, and for non-brand-name drugs it is AMP minus 11%. *See supra* note 15.

with respect to eliminating manufacturers' best-price manipulation — the only realistic means by which manufacturers engage in overcharges. Such a parallel action by the entities that Congress specifically intended to benefit in § 256b and that bear the full brunt of manufacturers' overcharges complements any federal enforcement efforts. It also vindicates the congressional objective of ensuring that covered entities have access to the best pharmaceutical prices in stretching scarce governmental resources to provide medical services for the neediest persons.

CONCLUSION

The judgment of the court of appeals should be affirmed.

Respectfully submitted,

MIGUEL MÁRQUEZ
COUNTY COUNSEL
GRETA S. HANSEN
JUNIPER L. DOWNS
JAMES R. WILLIAMS
OFFICE OF THE COUNTY COUNSEL
COUNTY OF SANTA CLARA
70 West Hedding Street
East Wing, 9th Floor
San Jose, California 95110
(408) 299-5900

DAVID C. FREDERICK
Counsel of Record
SCOTT H. ANGSTREICH
SCOTT K. ATTAWAY
KELLOGG, HUBER, HANSEN, TODD, EVANS & FIGEL, P.L.L.C.
1615 M Street, N.W.
Suite 400
Washington, D.C. 20036
(202) 326-7900
(dfrederick@khhte.com)

SANFORD SVETCOV
JEFFREY W. LAWRENCE
SUSAN K. ALEXANDER
AELISH M. BAIG
ROBBINS GELLER RUDMAN & DOWD LLP
100 Pine Street, 26th Floor
San Francisco, California 94111
(415) 288-4545

December 13, 2010