No. 09-1273

In the Supreme Court of the United States

ASTRA USA, INC., ET AL., PETITIONERS

v.

SANTA CLARA COUNTY, CALIFORNIA

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE SUPPORTING PETITIONERS

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QUESTION PRESENTED

Section 340B of the Public Health Service Act, 42 U.S.C. 256b, instructs the Secretary of Health and Human Services to enter into a Pharmaceutical Pricing Agreement (PPA) with drug manufacturers, in which the manufacturers pledge to offer discounted prices to certain healthcare providers known as "340B entities."

Respondent operates several 340B entities, and it alleges that petitioners—drug manufacturers that entered into the PPA—improperly charged prices higher than those permitted under the PPA. The question presented is whether respondent may bring a third-party breach-of-contract action to enforce petitioners' obligations under the 340B Program.

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INTEREST OF THE UNITED STATES

This case concerns the pharmaceutical pricing program established in 42 U.S.C. 256b and known as the 340B Program. The Department of Health and Human Services (HHS) administers the 340B Program, as well as the closely related Medicaid Rebate Program, see 42 U.S.C. 1396r-8. Accordingly, the United States has a substantial interest in the issues presented in this case.

STATEMENT

1. a. The Medicaid program, established by Title XIX of the Social Security Act (the Medicaid Act), 42 U.S.C. 1396 *et seq.*, is a cooperative federal-state program that provides medical assistance to certain low-

income individuals.[1] *Harris* v. *McRae*, 448 U.S. 297, 301 (1980). In order to participate in the Medicaid program, a State must have a plan for medical assistance that has been approved by HHS's Centers for Medicare & Medicaid Services (CMS), which administers the federal Medicaid program. 42 U.S.C. 1396a (2006 & Supp. II 2008). As part of a State's Medicaid plan, a State may offer outpatient prescription drug coverage. 42 U.S.C. 1396d(a)(12).

The Medicaid Rebate Program, established in 1990, establishes the framework governing Medicaid coverage of prescription drugs. See Omnibus Budget Reconciliation Act, Pub. L. No. 101-508, § 4401, 104 Stat. 1388-143 (codified as amended at 42 U.S.C. 1396r-8). Drug manufacturers seeking to have their drugs covered by Medicaid must enter into agreements with HHS to provide rebates to the States on their sales of prescription drugs covered by Medicaid. 42 U.S.C. 1396r-8(a)(1); see *Pharmaceutical Research & Mfrs. of Am.* v. *Walsh*, 538 U.S. 644, 652 (2003).

The terms of each Medicaid rebate agreement are dictated by statute, and they obligate the manufacturer to pay specified rebates to the States, determined pursuant to a formula set forth in Section 1396r-8(c). For single-source and innovator multiple-source drugs (essentially, brand-name drugs), the rebate due on each drug unit is typically the difference between the "average manufacturer price" (AMP) and the manufacturer's

[1] The Patient Protection and Affordable Care Act (PPACA), Pub. L. No. 111-148, 124 Stat. 119 (2010), made significant changes to the Medicaid Act and the 340B Program. Unless otherwise noted, references to the Medicaid and 340B statutes are to the pre-PPACA law in effect at the time of the court of appeals' decision.

"best price" (Best Price), or a defined percentage of AMP, whichever is greater. 42 U.S.C. 1396r-8(c)(1)(A), (B), (C) and (c)(2). For other drugs, the rebate is a percentage of AMP. 42 U.S.C. 1396r-8(c)(3).

Until October 1, 2010, a drug's AMP was defined as "the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade."[2] 42 U.S.C. 1396r-8(k)(1)(A). A drug's Best Price is generally the "lowest price available from the manufacturer during [the relevant time period] to any" private purchaser or governmental entity. See 42 U.S.C. 1396r-8(c)(1)(C).

Manufacturers are required to calculate AMP and Best Price and report those figures to CMS, which then uses these data to calculate the unit rebate amount for each drug. See 42 U.S.C. 1396r-8(b)(3)(A). CMS has promulgated comprehensive regulations instructing manufacturers on how to calculate AMP and Best Price. See 42 C.F.R. 447.500 to 447.520.[3] Because the reported AMP and Best Price are sensitive trade information, the Medicaid Act prohibits HHS from disclosing the information "in a form which discloses the identity of a specific manufacturer * * * [, or] prices charged for drugs by such manufacturer," except in enumerated situations. 42 U.S.C. 1396r-8(b)(3)(D).

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[2] Effective October 1, 2010, the PPACA amends the definition of AMP by tying its calculation to prices charged to "retail community pharmacies." Pub. L. No. 111-148, § 2503(a)(2) and (d), 124 Stat. 310, 312.

[3] In order to comply with the PPACA, CMS has withdrawn its regulations pertaining to the definition of AMP, and will issue regulations regarding the PPACA's amended definition. 75 Fed. Reg. 69,591-69,597 (2010).

b. The Medicaid Act and the rebate agreement provide HHS with comprehensive measures to enforce manufacturers' statutory obligation to accurately report AMP and Best Price to CMS. HHS may audit manufacturers' calculations, 42 U.S.C. 1396r-8(b)(3)(A)-(B), may impose monetary penalties for knowing violations, 42 U.S.C. 1396r-8(b)(3)(B)-(C), and may seek other remedies provided by law, 42 U.S.C. 1396r-8(b)(3)(C)(ii). Under the Medicaid rebate agreement, CMS also may require manufacturers to correct erroneous data and make additional rebate payments to States. J.A. 81. Finally, CMS may terminate a manufacturer's participation in the program because of "violation[s] of * * * the agreement or other good cause." 42 U.S.C. 1396r-8(b)(4)(B)(i).

2. a. The 340B Program is closely related to the Medicaid Rebate Program. In 1992, Congress became concerned that manufacturers, in an attempt to raise the Best Price figures for their drugs under Medicaid and lower their rebate payments to States, had reduced the discounts that they had been giving to safety-net providers that provide health care to underserved individuals. See H.R. Rep. No. 384, 102d Cong., 2d Sess. Pt. 2 at 10-12 (1992). Congress responded by creating the 340B Program to govern the drug prices that manufacturers may charge such entities. Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602, 106 Stat. 4967.

Codified at 42 U.S.C. 256b, the 340B statute directs HHS to enter into a Pharmaceutical Pricing Agreement (PPA) with each drug manufacturer that chooses to participate in the Program. See 42 U.S.C. 256b(a). Manufacturers who do not opt into the 340B Program lose eligibility for Medicaid coverage of their drugs. See 42

U.S.C. 1396r-8(a)(1) and (5). Section 256b(a)(1) requires that the PPA obligate manufacturers to charge health-care providers that are listed as "covered entities" (also known as "340B entities") prices that do not exceed the "ceiling price." 42 U.S.C. 256b(a)(1)-(2); see also Pet. App. 170a-171a. Section 256b defines the ceiling price for each drug with reference to the drug's AMP and Best Price. 42 U.S.C. 256b(a)(1)-(2). If a manufacturer overcharges covered entities, HHS may terminate the manufacturer's participation in the 340B Program. 42 U.S.C. 1396r-8(b)(4)(B)(v).

The PPA incorporates Section 256(b)'s requirements.[4] It provides that "[p]ursuant to requirements under section 340B of the Act, the Manufacturer agrees" to charge covered entities no more than the ceiling price described in Section 256b(a), based on the pricing data "reported * * * to the Secretary in accordance with the Manufacturer's responsibilities under [S]ection [1396r-8(b)(3)] of the [Medicaid Act]." Pet. App. 170a. The PPA also requires manufacturers to provide HHS with access to records to assure compliance with the pricing rules, and provides that manufacturers may invoke an informal dispute resolution process to resolve allegations that covered entities have sought duplicative discounts or otherwise violated their obligations under Section 256b(a)(5). *Id.* at 171a-175a. The PPA also permits HHS to invoke an adjudication process when it believes that a manufacturer has not complied with its obligations. *Id.* at 174a.

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[4] The language of the PPA has been revised over time, but the revisions are immaterial to this litigation. This brief relies on the version of the PPA reprinted at Pet. App. 165a-181a.

b. Within HHS, the 340B Program is administered by the Health Resources and Services Administration (HRSA). HRSA has established a voluntary dispute resolution process to resolve the disputes referred to in the PPA, and also to resolve "certain [other] disputes between manufacturers and covered entities concerning compliance with the provisions of" Section 256b. 61 Fed. Reg. 65,411 (1996). Covered entities that believe that a manufacturer is charging a price in excess of the ceiling price may invoke that procedure. *Id.* at 65,412. Upon finding that a manufacturer has failed to comply with its obligations, HRSA may order refunds to covered entities, Pet. App. 174a, or terminate the agreement. *Ibid.*; 61 Fed. Reg. 65,412-65,413.

c. In practice, the 340B Program generally works as follows: Manufacturers are responsible for calculating the ceiling price for each drug based on the AMP and Best Price that they have reported to CMS, as well as the instructions in Section 256b(a). Most drug sales to covered entities are routed through wholesalers, see Office of the Inspector General (OIG), HHS, *Review of 340B Prices* 2 (July 2006) (*340 Report*), so manufacturers generally instruct wholesalers to charge covered entities the manufacturer-calculated ceiling price. The wholesalers do so, often adding a distribution fee.

Independently, HRSA calculates the ceiling price for each drug based on the reported AMP and Best Price. *340B Report* 3; Gov't Accountability Office, *Prescription Drugs: Oversight of Drug Pricing in Federal Programs* 5 (2007) (*Oversight Report*). HRSA's calculated ceiling price should be equal to the ceiling price that the manufacturer provided to wholesalers. But the Medicaid Act's confidentiality provision prohibits HHS from re-

vealing manufacturers' reported AMP and Best Price, as well as the ceiling price that HRSA has calculated based on those figures. See 42 U.S.C. 1396r-8(b)(3)(D). As a result, although covered entities naturally are aware of the price that they have been charged for each drug, *i.e.*, the price that the manufacturer claims is the correct ceiling price, they have no way of verifying whether the manufacturer's selling price accords with HRSA's calculations, or whether it is based on accurate AMP and Best Price figures. *Oversight Report* 5 & n.11. A covered entity may, however, ask that HRSA verify that the entity is not being overcharged. HRSA has informed this Office that although covered entities do not often utilize this procedure, when they do, HRSA is often able to resolve overcharges informally with the manufacturers.

3. In March 2010, Congress enacted the Patient Protection and Affordable Care Act (PPACA), which made significant changes in the 340B Program. Pub. L. No. 111-148, §§ 7101-7102, 124 Stat. 821-827. In addition to increasing the scope of the program by adding new categories of covered entities, the PPACA directs HHS to institute a comprehensive administrative process to adjudicate and remedy violations of the 340B Program's requirements for purchases after January 1, 2010, § 7102(a), 124 Stat. 823-827, subject to judicial review pursuant to the Administrative Procedure Act (APA), 5 U.S.C. 701 *et seq*. The PPACA also instructs HHS to develop procedures by which manufacturers may be required to refund overcharges to covered entities and to pay civil monetary penalties for intentional violations. § 7102(a), 124 Stat. 824.

To comply with the PPACA's mandate, HHS has issued advance notices of proposed rulemaking soliciting

comments on HHS's development of the civil monetary penalty scheme and the administrative adjudication process. See 75 Fed. Reg. 57,230 (2010); *id.* at 57,233.

4. a. In 2005, respondent, which operates several 340B entities, brought this action in California state court on behalf of a putative class of 340B entities. Pet. App. 6a; J.A. 1, 28-30, 56. Respondent alleged that petitioners—drug manufacturers that participate in the 340B Program—had charged respondent prices that exceeded the ceilings established by the PPA. J.A. 47-49, 50-56. Among other claims, respondent asserted a breach-of-contract action premised on its purported status as an intended third-party beneficiary of the PPA. J.A. 63-65. After the case was removed to federal court, the district court dismissed the complaint, concluding, among other things, that the PPA did not reflect any intent to confer enforcement rights on 340B entities. Pet. App. 98a, 113a-119a.

b. The court of appeals reversed and remanded. Pet. App. 36a. The court first concluded that respondent was an intended third-party beneficiary of the PPA because the agreement was executed for the purpose of regulating the prices that petitioners may charge covered entities. *Id.* at 41a-43a. In the court's view, it necessarily followed that respondent had the right to bring suit under the PPA, because "the right to sue inheres in one's status as an intended beneficiary." *Id.* at 39a, 41a-50a. Permitting the suit would be consistent with the statutory scheme despite the lack of any private right of action to enforce Section 256b itself, the court reasoned, because Congress's failure to accord 340B entities statutory remedies reflected its intent not to "displace" any federal common law enforcement rights arising from the

PPA. *Id.* at 51a-54a. Finally, the court held that referral to HHS under the doctrine of primary jurisdiction was unnecessary because the PPA entitled covered entities "only to the [AMP] *reported* to the Secretary," and respondent "cannot claim that the reported figure was itself somehow erroneous" under HHS's regulations. *Id.* at 57a.

c. On remand, the district court held that the court of appeals' opinion precluded respondent from challenging the accuracy of petitioners' calculations of AMP and Best Price. Pet. App. 90a. The court of appeals accepted an interlocutory appeal from that ruling, see 28 U.S.C. 1292(b), and invited the United States to file an amicus brief. Pet. App. 90a.

The government argued, *inter alia*, that the PPA requires manufacturers to calculate the ceiling price based on AMP and Best Price figures correctly reported in accordance with the Medicaid rebate framework. Gov't C.A. Br. 15-17. The government explained, however, that permitting respondents to challenge those figures or ceiling prices in a third-party beneficiary suit would conflict with the PPA and the statutory scheme. *Id.* at 17-21. Finally, the government stated that, given HHS's expertise in the comprehensive framework governing AMP and Best Price, referring the dispute to HHS under the primary jurisdiction doctrine might be appropriate once the nature of respondent's allegations became clearer. *Id.* at 22-32.

The court of appeals reissued its original opinion with a revised discussion of primary jurisdiction that omitted the suggestion that ceiling prices were tied to reported AMP and Best Price. Pet. App. 2a, 27a-29a.

SUMMARY OF ARGUMENT

The court of appeals' ruling that 340B entities may enforce manufacturers' obligations under the 340B Program through breach-of-contract suits is inconsistent with the statutory framework and, in particular, Congress's decision to vest enforcement authority in HHS.

I. The PPACA materially alters the 340B statutory framework by establishing a comprehensive administrative procedure to resolve claims by covered entities and to provide refunds and other remedies for violations. This procedure is intended to be exclusive, and although it will not apply to the claims at issue in this case, its enactment demonstrates that Congress regards the 340B Program as essentially statutory and regulatory—not contractual—in nature.

II. The court of appeals erred in treating the PPA as a transactional contract that can give rise to third-party beneficiary rights. The PPA is a regulatory mechanism that embodies the relevant provisions of the Medicaid and 340B Acts, including the price calculation rules that respondent alleges petitioners have violated, with respect to manufacturers that have opted in to the 340B Program. Manufacturers' rights and obligations flow from the statutory framework, not from bargained-for contract terms that have independent legal significance. As a result, the PPA does not give rise to enforceable third-party-beneficiary rights through the operation of the contract-law principles that might apply to an ordinary transactional contract. Respondent's entitlement to enforce the PPA must therefore arise from the statute, but as respondent acknowledged below, the 340B Act does not provide a right of action.

III. Even if the PPA is viewed as a traditional bilateral contract, the court of appeals erred in concluding that the PPA creates enforceable third-party beneficiary rights. The question whether a contract entered into by an agency creates enforceable third-party beneficiary rights depends on two inquiries: first, Congress must have authorized the agency to confer contract-enforcement rights on third parties; and second, the agency must have done so in the particular contract at issue. Here, even if HHS has the authority to confer third-party beneficiary rights in the PPA, there can be no question that it has not done so. The PPA's text demonstrates that the parties did not intend to permit potentially thousands of covered entities to bring suits alleging errors in manufacturers' price calculations. Construing the PPA to confer third-party rights would also be inconsistent with the statutory framework. The Medicaid Act's confidentiality provision bars covered entities from obtaining the information that would be necessary to determine whether manufacturers have violated their obligations. Moreover, the Medicaid Act and Section 256b contain a number of provisions that vest enforcement authority in HHS. That reflects Congress's intent that HHS should be permitted to determine the manufacturers' obligations in the first instance, in light of its expertise in, and responsibility for, both programs.

ARGUMENT

I. THE PATIENT PROTECTION AND AFFORDABLE CARE ACT ESTABLISHES A COMPREHENSIVE REMEDIAL SCHEME THAT, ONCE IMPLEMENTED, WILL PROVIDE THE EXCLUSIVE REMEDY FOR COVERED ENTITIES' OVERCHARGE CLAIMS

The court of appeals adjudicated the question presented—whether covered entities are intended third-party beneficiaries who may enforce drug manufacturers' obligations under the 340B Program—in light of the statutory framework in place at the time. Subsequent to the court's decision, Congress enacted the PPACA, which directs HHS to establish a comprehensive adjudicative and remedial framework to govern overcharge claims by 340B entities. See PPACA, Pub. L. No. 111-148, 124 Stat. 119. That framework will henceforth provide the exclusive remedy for covered entities.

Thus, with respect to claims relating to drugs purchased on or after January 1, 2010, § 7101(e), 124 Stat. 823, HHS must develop procedures to perform audits of manufacturers' reported ceiling prices; provide covered entities with remedies for "overcharges and other violations of the discounted pricing requirements"; and implement a civil monetary penalty system for knowing violations. § 7102(a), 124 Stat. 823-827. HHS also must institute an administrative adjudication process to resolve claims by covered entities (and manufacturers), and must develop procedures to resolve such claims expeditiously; to permit covered entities to obtain some discovery of information from manufacturers and third parties; and to permit joinder of claims and parties.

Ibid. The agency's resolution of claims is binding and subject to judicial review under the APA. *Ibid.*

This Court has held that when Congress establishes an administrative remedial scheme to adjudicate claims under a statute, subject to judicial review of the agency's decision, "Congress has allocated initial review to an administrative body" and has demonstrated its intent "to direct ordinary challenges under [the statute] to a single review process." *Thunder Basin Coal Co.* v. *Reich*, 510 U.S. 200, 207-209, 211-213 (1994). The PPACA's review provisions reflect just this intent, by according HHS the initial opportunity to apply its expertise in determining manufacturers' obligations under the statutory framework, and by providing broad authority to remedy violations. See *id.* at 207-208.

Respondent's breach-of-contract claim is precisely the type of claim that Congress intended should be channeled through the new review process in the future. Claims that manufacturers have failed to properly calculate AMP, Best Price, and the ceiling price "at root require interpretation of the parties' rights and duties under" the Medicaid Act, Section 256b, and HHS's regulations, thus "fall[ing] squarely within [HHS's] expertise." *Thunder Basin*, 510 U.S. at 214. Permitting covered entities instead to bring a breach-of-contract action directly in court would therefore be inconsistent with congressional intent underlying the new comprehensive framework. See *Shalala* v. *Illinois Council on Long Term Care, Inc.*, 529 U.S. 1, 13 (2000) (according the agency an "opportunity to apply, interpret, or revise policies, regulations, or statutes without possibly premature interference by different individual courts" is particularly important in the context of a complex regula-

tory program). Moreover, Congress's provision of the administrative adjudication scheme, and its corresponding preclusion of claims that bypass that scheme, will necessarily be incorporated in the PPA, so any enforcement rights that respondent might have under the PPA will be limited to seeking relief in accordance with the statutory scheme. Cf. *United States* v. *Erika, Inc.*, 456 U.S. 201, 211 n.14 (1982) (statutory preclusion of review would be incorporated in agreements under the statute, and therefore would preclude a third-party beneficiary suit).

Although the administrative review framework to be established under the PPACA will not apply to the claims at issue in this case, the enactment of that framework demonstrates that Congress regards the 340B Program as essentially statutory and regulatory—not contractual—in nature. See pp. 14-21, *infra*. Suits by covered entities on a contractual third-party-beneficiary theory are out of place under such a program. As we explain below, the statutory and regulatory nature of the 340B Program was evident prior to enactment of the PPACA, and likewise provides no basis for respondent's suit on a contractual third-party-beneficiary theory.

II. THE PPA DOES NOT CREATE CONTRACTUAL RIGHTS IN REGULATED ENTITIES BECAUSE IT IS A REGULATORY MECHANISM OF IMPLEMENTING THE STATUTORY SCHEME WITH RESPECT TO DRUG MANUFACTURERS THAT CHOOSE TO PARTICIPATE

The court of appeals viewed the PPA as an ordinary bilateral contract between the government and drug manufacturers, and therefore assumed that the PPA gives rise to ordinary contractual relationships between

the government and manufacturers, and with covered entities as intended third-party beneficiaries. Pet. App. 8a-13a. This conception misapprehends the nature of the PPA and its function within the statutes that Congress has enacted in this area. The PPA "cannot be viewed in the same manner as a bilateral contract governing a discrete transaction." *Bennett* v. *Kentucky Dep't of Educ.*, 470 U.S. 656, 669 (1985). Rather, the PPA is part of the regulatory program established by Section 256b: it incorporates the terms and conditions set forth in Section 256b and the Medicaid Rebate Program, 42 U.S.C. 1396r-8, and applies them to manufacturers that opt to participate in the 340B Program. The obligations imposed by the PPA are therefore statutory and regulatory—not contractual—in nature, and the PPA does not give rise to enforceable contractual rights in manufacturers or in covered entities as third-party beneficiaries.

A. The 340B Program is structured as an opt-in program in which drug manufacturers may voluntarily choose to participate. Section 256b(a)(1) directs HHS to "enter into an agreement with each manufacturer of covered drugs" that decides to participate. 42 U.S.C. 256b(a)(1). The agreement must require the manufacturer to charge covered entities a price that "does not exceed" the ceiling price, which the statute defines as the AMP reduced by the rebate percentage, calculated in accordance with cross-referenced provisions of the Medicaid Act. See 42 U.S.C. 256b(a)(1)-(2) and (b), 1396r-8(c). The remainder of Section 256b sets forth the other conditions of the 340B Program. The statute defines the class of covered entities eligible to receive discounts under the 340B Program; prohibits covered enti-

ties from, among other things, seeking duplicative discounts; and establishes compliance procedures. 42 U.S.C. 256b(a)(4) and (5). In addition, the Medicaid Act gives HHS the authority to terminate manufacturers' agreements under the 340B Program, see 42 U.S.C. 1396r-8(b)(4)(B)(v), and requires HHS to keep confidential any manufacturer information that is reported to HHS under the Medicaid Rebate Program and used in the 340B Program, see 42 U.S.C. 1396r-8(b)(3)(D).

B. In order to implement Section 256b, HHS created the PPA, which manufacturers must sign in order to participate in the 340B Program. See 58 Fed. Reg. 27,291 (1993). The PPA's primary terms incorporate the statutory calculation methods and reporting requirements established by Section 256b. Specifically, the PPA provides that "[p]ursuant to requirements under section 340B of the Act, the Manufacturer agrees" to charge covered entities the ceiling price described in Section 256b(a), based on the pricing data "reported * * * to the Secretary in accordance with the Manufacturer's responsibilities under [S]ection [1396r-8(b)(3)] of the [Medicaid Act]." Pet. App. 170a.[5] The PPA thus incorporates manufacturers' statutory obligation to accurately report AMP and Best Price in accordance with the standards set forth in the Medicaid Act and its regulatory framework, and also incorporates Section 256b(a)(1)'s requirement that manufacturers calculate

[5] Manufacturers also agree to certain recordkeeping requirements to permit HHS to verify compliance; for the most part, these requirements are duplicative of manufacturers' obligations under the Medicaid Rebate Program. See 42 U.S.C. 1396r-8(b)(3)(A), 42 C.F.R. 447.510(f); Pet. App. 171a.

the statutory ceiling price based on the accurately reported AMP and Best Price.

Respondent's claims in this case underscore that the manufacturers' obligations under the PPA arise from the statutory framework, rather than any separate terms created by agreement between the manufacturer and HHS. Respondent alleges that petitioners breached the PPA by reporting improperly calculated AMP and Best Price and charging more than the 340B ceiling price, see J.A. 41-42, 44-45; Br. in Opp. 8-10—not that petitioners violated any independent substantive obligation arising only from the PPA. When a party's obligations under an agreement with an agency simply embody statutory requirements, the natural inference is that "Congress did not intend that contract principles govern the interpretation of the relationship between the Secretary" and regulated entities, and the agreement does not give rise to contractual rights in the regulated parties. *Rendleman* v. *Bowen*, 860 F.2d 1537, 1542 (9th Cir. 1988); see *Aiken* v. *United States*, 4 Ct. Cl. 685, 692 (1984); *American Hosp. Ass'n* v. *Schweiker*, 721 F.2d 170, 182-183 (7th Cir. 1983), cert. denied, 466 U.S. 958 (1984).

Moreover, the PPA's terms, unlike those of an ordinary transactional contract, remain subject to Congress's and HHS's authority to alter them by enacting legislation or promulgating regulations. See *Bowen* v. *Public Agencies Opposed to Soc. Sec. Entrapment*, 477 U.S. 41, 55 (1986) (*POSSE*) (because "Congress retained authority to amend" a provision in a federal-state agreement, the provision did not create vested contractual rights); *National R.R. Passenger Corp.* v. *Atchison, Topeka & Santa Fe Ry.*, 470 U.S. 451, 465 (1985) (*Atchi-*

son). For example, Congress has altered manufacturers' obligations under the PPA by expanding the statutory definition of "covered entity" in Section 256b(a)(4). See, *e.g.*, Pub. L. No. 111-148, § 7101, 124 Stat. 821-823; Pet. App. 167a (defining "covered entity" as the entities listed in Section 256b(a)(4)). Similarly, the method by which manufacturers are required to calculate the ceiling price under the PPA can be altered by amending the provisions of the Medicaid Rebate Program, see *id.* at 170a; 42 U.S.C. 1304, or CMS's regulations, see, *e.g.*, 75 Fed. Reg. at 69,591-69,597 (withdrawing regulation governing AMP).

The terms of the PPA, moreover, are not the product of negotiation between the parties—the PPA is a form agreement to which manufacturers must agree in full. Compare *Rendleman*, 860 F.2d at 1541. The PPA's provisions also do not reflect an exchange of reciprocal obligations or of items or services of value between the parties (or any other bargained-for consideration); for example, the information-sharing and other obligations of HHS that are recited in the PPA are intrinsic to the agency's responsibility for administering the statutory scheme. See Pet. App. 172a. Thus, the primary benefit to the manufacturer arising from the PPA is statutory: under the Medicaid Act, a manufacturer's drugs will not be included in the Medicaid Rebate Program unless the manufacturer opts into the 340B Program. See 42 U.S.C. 1396r-8(a)(1) and (5).

Similarly, HHS's power to enforce obligations incorporated in the PPA has the character of administrative enforcement. The PPA reiterates HHS's statutory right to terminate the agreement if it determines that a manufacturer has charged a price that exceeds the ceiling

price or has otherwise failed to comply with statutory requirements.[6] See Pet. App. 174a; 42 U.S.C. 1396r-8(b)(4)(B)(v). The PPA also provides that HHS may order a manufacturer to reimburse a covered entity for "discounts withheld," Pet. App. 174a, and provides for informal agency adjudication of manufacturers' claims against covered entities for violating statutory provisions in Section 256b(a)(5). *Id.* at 173a-174a; 42 U.S.C. 256b(a)(5)(A). As noted above, Congress confirmed in the PPACA that the drug manufacturers' obligations are statutory, and that the overall 340B framework is regulatory, not contractual, by directing HHS to create a formal, mandatory adjudication process to resolve the claims of both manufacturers and covered entities, subject to APA review. See pp. 12-14, *supra.*

C. In sum, the PPA is the mechanism by which Congress and HHS effectuate "regulatory policy," rather than "a contractual arrangement" that gives rise to bargained-for contractual rights in the regulated parties. *Atchison*, 470 U.S. at 465; see *POSSE*, 477 U.S. at 55. In analogous situations, courts have concluded that Congress's use of an agreement to facilitate participation in, and mark entry into, a regulatory scheme does not create contractual rights in the regulated entities.

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[6] The United States also may sue to enforce manufacturers' compliance with the terms and conditions of the 340B Program as an incident to their receipt of federal Medicaid funds. See *United States* v. *Marion County Sch. Dist.*, 625 F.2d 607, 609-610 (5th Cir. 1980), cert. denied, 451 U.S. 910 (1981); cf. *Bennett*, 470 U.S. at 669 (federal grant program was not purely contractual in nature, but the government may seek reimbursement of federal funds when State has violated its obligations); *Bell* v. *New Jersey*, 461 U.S. 773, 793-794 (1983) (White, J., concurring) (government is entitled to enforce funding conditions).

See, *e.g.*, *id.* at 55 (termination provision in federal-state agreements to provide Social Security benefits to state employees under 42 U.S.C. 418 was "part of a regulatory program"); *Hollander* v. *Brezenoff*, 787 F.2d 834, 838-839 (2d Cir. 1986) ("Congress—when enacting [S]ection 1396a(a)(27) of the Social Security Act—did not aim to create a contract cause of action for the benefit of providers, but simply sought to facilitate the processing and transmission of information by providers supplying services under the Medicaid plan."); *Memorial Hosp.* v. *Heckler*, 706 F.2d 1130, 1136-1137 (11th Cir. 1983), cert. denied, 465 U.S. 1023 (1984); *Rendleman*, 860 F.2d at 1542; *American Hosp. Ass'n*, 721 F.2d at 182-183; *Aiken*, 4 Ct. Cl. at 692. It follows that the PPA does not give rise to enforceable third-party beneficiary rights through the operation of contract-law principles.

This conclusion is buttressed by the well-established principle that statutory benefits under the Social Security Act (of which the Medicaid Act is a part) do not give rise to contractual rights in program beneficiaries and participating entities, absent a clear indication of congressional intent to incorporate contract law. See *POSSE*, 477 U.S. at 52; *Flemming* v. *Nestor*, 363 U.S. 603, 608-611 (1960); cf. *United States R.R. Ret. Bd.* v. *Fritz*, 449 U.S. 166, 174 (1980). This principle flows from Congress's need to have continuing flexibility in adjusting benefits and modifying the programs in response to changing conditions. See *Flemming*, 363 U.S. at 610-611. There is no reason to think that Congress would eschew such flexibility in the 340B Program. Congress's use of an agreement as a regulatory mechanism does not itself suggest that Congress intended to provide, *sub silentio*, for the conferral of contract rights on

manufacturers and thousands of 340B entities. See, *e.g.*, *POSSE*, 477 U.S. at 45; *Hollander*, 787 F.2d at 838-839.

Thus, if respondent has any right to enforce petitioners' obligations under the 340B Program, that right must arise from the statute or from regulations promulgated pursuant to a congressional grant of authority, not from the imposition of non-textual contract-law principles on the 340B Program and the PPA. See *Alexander* v. *Sandoval*, 532 U.S. 275, 291 (2001). As respondent conceded below, there is no private right of action to enforce Section 256b. See Pet. App. 50a. The recent amendments to Section 256b, directing HHS to create an administrative adjudication process, confirm Congress's intent that drug manufacturers' obligations be enforced in the first instance by the agency, not a court. Respondent therefore may not privately enforce petitioners' obligations under the 340B Program and the PPA.

III. EVEN IF THE PPA IS REGARDED AS A CONTRACT, RESPONDENT DOES NOT HAVE A THIRD-PARTY BENEFICIARY RIGHT TO ENFORCE IT

For the reasons discussed above, the court of appeals erred in analyzing the PPA as a run-of-the-mine contract that can serve as a source of third-party beneficiary enforcement rights. Even taken on its own terms, however, the court's decision is incorrect. Viewed as a contract, the PPA does not confer on 340B entities the right to enforce manufacturers' obligation to charge the correct ceiling price. The PPA does not manifest the requisite intent to accord enforcement rights to 340B entities, and construing the agreement to do so would be inconsistent with the statutory scheme and harmful to

HHS's administration of the 340B and Medicaid Rebate Programs.

A. The Existence Of Third-Party Beneficiary Rights Turns On Congressional Authorization And The Agency's Intent In Entering Into The Contract

When Congress authorizes an agency to enter into a contract, the question whether third parties may sue to enforce the contract depends on two related inquiries. First, Congress must have authorized the contracting agency to create third-party rights in the contract at issue. Second, the agency must have exercised its statutory authority by manifesting an intent to permit third parties to enforce the contract.

1. When Congress confers on an agency the authority to enter into contracts to implement a statute, Congress may also confer on the agency the authority to agree that third parties may enforce the contract. Cf. *Hercules, Inc.* v. *United States*, 516 U.S. 417, 426-428 (1996) (agency's authority to agree to specific contract terms is limited by statute). Whether Congress has conferred that authority on the agency is a question that is related to, but distinct from, the question whether Congress has rendered the statute itself directly enforceable through an express or implied right of action. Congress might reasonably decide that although a statute should not be directly enforceable by private parties, the agency should have discretion to grant third parties the right to enforce specific provisions of a contract entered into pursuant to the statute. Cf. *Sandoval*, 532 U.S. at 291 ("when a statute has provided a general authorization for private enforcement of regulations," an agency may be able to provide such rights). Whether Congress

has conferred on the agency the authority to create enforceable third-party beneficiary rights in a contract executed pursuant to a federal statute is a question of congressional intent with respect to the statute and the contract at issue.[7] See *Jackson Transit Auth.* v. *Local Div. 1285*, 457 U.S. 15, 22 (1982).

Although the absence of an express or implied right of action under the statute itself need not be dispositive of the agency's authority to create third-party contract enforcement rights, it is certainly relevant. That is particularly true when the contract simply incorporates statutory obligations, such that a third-party suit to enforce the contract would in essence seek to enforce the requirements imposed by the statute. Parties may privately enforce federal statutes only to the extent authorized by Congress, see *Mertens* v. *Hewitt Assocs.*, 508 U.S. 248, 255 n.5 (1993), and the factors that can lead a court to determine that a direct private right of action should not be inferred are relevant to the question whether Congress intended to permit the agency to grant third-party beneficiary rights by contract. For instance, when the lack of a right of action reflects Congress's intent that enforcement of the statutory scheme should be vested only in the government, and a third-party suit to enforce the contract would simply enforce statutory terms, permitting such a suit would have the effect of allowing third parties to circumvent Congress's decision not to permit private enforcement of the stat-

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[7] This individualized inquiry is particularly necessary in view of the varying contexts in which Congress grants agencies the authority to enter into agreements that contain terms pertaining to third parties. See, *e.g.*, 42 U.S.C. 1437f; 49 U.S.C. 5333(b); 38 U.S.C. 4212; 42 U.S.C. 418.

ute. In that situation, an agency's granting of third-party contract rights would be inconsistent with congressional intent. See *Erika*, 456 U.S. at 211 n.14.

2. When Congress has delegated to the agency the authority to confer third-party contract enforcement rights, the existence of those rights then turns on whether the agency has exercised its authority in the contracts at issue. Cf. *Aluminum Co. of Am.* v. *Central Lincoln Peoples' Util. Dist.*, 467 U.S. 380, 400 (1984) (agency has discretion to determine terms of contract, consistent with congressional intent).

In the context of contracts between an agency and other parties, a court should find that the contracting parties intended to confer enforceable rights on third parties only if the intent to permit third-party enforcement is clear. Under traditional contract principles, a contract confers enforceable rights on third parties only if those parties are intended, rather than incidental, beneficiaries of the contract, and only if "recognition of a right to performance in the beneficiary is appropriate to effectuate the intention of the parties."[8] Restatement (Second) of Contracts § 302(1) (1981) (Restatement).

Thus, even when the contract is intended to benefit a discrete class of parties, the parties must have intended "to confer on a third party an enforceable right concerning which the promisee and the promisor bargained." 13 Samuel Williston & Richard A. Lord, *A*

[8] Federal common law governs contracts that are entered into by an agency pursuant to a federal statute, see *United States* v. *Seckinger*, 397 U.S. 203, 209-210 (1970), but the Court may use traditional rules of contract law to guide its determination of federal law, as long as those rules are consistent with federal statutes and policies. See *Textile Workers Un.* v. *Lincoln Mills*, 353 U.S. 448, 456-457 (1957).

Treatise on the Law of Contracts § 37:8, at 79 (4th ed. 2000). This latter requirement is rigorously enforced in the context of government contracts. See Restatement § 313, cmt. a; 9 John E. Murray, Jr., *Corbin on Contracts* § 45.6, at 92 (rev. ed. 2007) ("The distinction between an intention to benefit a third party and an intention that the third party should have the right to enforce that intention is emphasized where the promisee is a governmental entity."); see also *German Alliance Ins. Co.* v. *Home Water Supply Co.*, 226 U.S. 220, 230-231 (1912).

When government contracts operate as part of a broader statutory and regulatory scheme, the Restatement provides that a court, in assessing the intent of the parties, should not permit third-party enforcement "to the extent that application would contravene the policy of the law authorizing the contract or prescribing remedies for its breach." Restatement § 313(1). Therefore, congressional intent with respect to third-party enforcement of the statutory scheme is also relevant at this stage of the third-party-beneficiary analysis, as is the potential for third-party suits to disrupt an agency's ability to act as a centralized regulator. These considerations in turn bear on the agency's intent in contracting and whether the contract should be construed to confer enforceable third-party rights.

B. The PPA Does Not Grant Respondent The Right To Enforce Petitioners' Obligations

This Court need not decide whether Section 256b, as it existed at the time the PPA was drafted, permitted HHS to confer third-party beneficiary rights to enforce the manufacturers' obligations. Even if the statutory

scheme is construed not to foreclose HHS from doing so, and even if 340B entities are assumed to be direct beneficiaries of the PPA, there can be no question that the PPA does not manifest any intent to grant 340B entities the right to enforce petitioners' obligations. As discussed above, see pp. 16-17, *supra*, the terms of the PPA upon which respondent relies are in fact incorporations of statutory requirements, rather than independent provisions of the contract. Construing the PPA to confer such enforcement rights would be in considerable tension with Congress's evident intent—confirmed by the amendments to the 340B scheme enacted in the PPACA—to concentrate enforcement authority in the government, whether under the PPACA, the False Claims Act, or otherwise.

1. a. The text of the PPA demonstrates that the parties did not intend to grant covered entities any enforceable contract rights. The PPA confers enforcement authority solely on HHS: the agency may at its discretion invoke the regulatory dispute resolution process in order to ensure that manufacturers comply with their obligations. Pet. App. 174a. When HHS initiates that procedure and finds that the manufacturer has overcharged covered entities, it may require the manufacturer to reimburse covered entities. *Ibid.* That is the primary relief that respondent seeks through its breach-of-contract claim.

Notably, the PPA itself does not provide covered entities with any mechanism to invoke the voluntary dispute resolution procedure. Indeed, the PPA does not explicitly contemplate any claims by covered entities, even as it permits manufacturers to request that HHS adjudicate covered entities' compliance with Section

256b(a)(5). Pet. App. 173a. HHS has accorded covered entities the ability to request dispute resolution if they believe they have been overcharged—but HHS established that right through regulatory guidance, not the PPA. See 61 Fed. Reg. 65,412. HHS thus has never viewed the PPA as governing covered entities' remedies.

The PPA's remedial savings clause confirms this interpretation. That provision states that the agreement's dispute resolution mechanism does not "preclude the *Manufacturer* or the *Secretary* from exercising such other remedies as may be available by law." Pet. App. 175a (emphases added). The absence of any mention of covered entities in this provision demonstrates that HHS, which prepared the PPA, and the manufacturers, which accepted it, did not view the PPA as giving rise to or governing any remedies for covered entities.

b. The industry backdrop against which the PPA was drafted also underscores that covered entities lack enforceable contract rights. Manufacturers generally do not distribute drugs directly to health-care providers; rather, they enter into distribution arrangements with wholesalers, which in turn sell to providers. See *340B Report* 2; David H. Kreling, *The Market for Pharmaceuticals: The Big Picture*, *in* Handbook of Pharmaceutical Public Policy 48 (Thomas R. Fulda & Albert I. Wertheimer eds., 2007). As a result, health-care providers that purchase pharmaceuticals generally have no direct contractual relationship with manufacturers, and a provider's remedies for overcharges ordinarily would not include a breach-of-contract action directly against the drug manufacturer.

The PPA works within this existing industry practice to govern the prices that manufacturers may charge

covered entities; it does not purport to regulate or alter the business relationships among industry actors. See OIG, HHS, *Deficiencies in the Oversight of the 340B Drug Pricing Program* 5 (Oct. 2005) (*2005 Report*); 58 Fed. Reg. at 27,291. Respondent thus acknowledges that it purchased its drugs from wholesalers, and that it has no contractual privity with petitioners.[9] Pl. Mot. for Joinder, Remand and/or Dismissal 8, 3:05-cv-03740, Docket entry No. 61 (N.D. Cal. Oct. 17, 2005). Absent a third-party beneficiary claim under the PPA, covered entities would ordinarily have no breach-of-contract remedy against manufacturers. Had the parties intended to alter these pre-existing relationships by granting covered entities the right to sue manufacturers directly, they would have made that intent manifest.

2. The Medicaid Act's prohibition on disclosure of manufacturers' pricing information to covered entities further indicates that the parties did not intend to create enforceable rights in covered entities. With certain exceptions, the Medicaid Act bars HHS from disclosing any pricing information in a form that could reveal the "prices charged for drugs by such manufacturer." 42 U.S.C. 1396r-8(b)(3)(D). HHS interprets this provision as prohibiting the agency from disclosing to covered entities the ceiling price that the agency calculates based on AMP and Best Price.[10] See 59 Fed. Reg. 25,110

[9] Covered entities sometimes contract directly with manufacturers, see *2005 Report* 4, for instance, when they negotiate prices that are lower than the ceiling price.

[10] In 2005, Congress amended the confidentiality requirement to permit HHS to disclose AMP figures on a publicly accessible website. See 42 U.S.C. 1396r-8(b)(3)(D)(v); Deficit Reduction Act, Pub. L. No. 109-171, § 6001, 120 Stat. 55. HHS was enjoined from disclosing these data

(1994); *Oversight Report* 5 & n.11; see also *Beck* v. *PACE Int'l Union*, 551 U.S. 96, 104 (2007) (agency interpretation of statute, expressed in amicus brief, is entitled to deference). As a result, covered entities have no way of determining whether the price that a manufacturer offers them is in fact the correct ceiling price. See *Oversight Report* 5. Indeed, respondent alleged as much in its complaint, stating that because HHS keeps pricing data confidential under Section 1396r-8(b)(3)(D), "[respondent] do[es] not possess and cannot without Court order obtain the information necessary to verify that the prices the Counties pay for prescription drugs are at or below the §340B ceiling price." J.A. 48-49.

As part of the governing statutory framework, the confidentiality requirement is incorporated into the PPA. See *Erika*, 456 U.S. at 211 n.14. The parties cannot have intended to grant 340B entities enforceable rights under the PPA in the face of a statutory provision that bars such entities from obtaining the very information necessary to determine whether their purported rights have been violated.

3. Construing the PPA to confer broad enforcement rights on covered entities also would be inconsistent

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as a result of a district court's finding that certain components of CMS's AMP definition were likely invalid. See *National Ass'n of Chain Drug Stores* v. *HHS*, 631 F. Supp. 2d 17, 18 (D.D.C. 2009). In any event, this exception does not apply to Best Price data, and therefore it does not suggest that the ceiling prices may be disclosed to covered entities.

Going forward, the PPACA will alter the confidentiality framework governing claims by 340B entities. In connection with the new administrative adjudication process, HHS must permit covered entities some discovery of information from manufacturers and third parties. Pub. L. No. 111-148, § 7102(a), 124 Stat. 826.

with Congress's decision to vest authority to enforce the Medicaid Rebate and 340B programs in the government, and would undermine HHS's ability to administer both programs.

The Medicaid Act contains a comprehensive remedial scheme that enables HHS to ensure that manufacturers accurately calculate and report AMP and Best Price—the bases of the 340B ceiling price calculation. HHS may audit and investigate manufacturers' calculations of AMP and Best Price, impose monetary penalties for inaccuracies, and terminate a manufacturer's participation in the Medicaid Rebate Program based on reporting errors or other good cause. 42 U.S.C. 1396r-8(b)(3)(A)-(C) and (4)(B). Beyond administrative enforcement, the government, in coordination with HHS, can pursue False Claims Act (FCA) actions, see 31 U.S.C. 3729 *et seq.*, and common-law fraud, unjust enrichment and similar actions, against manufacturers that evade their reporting obligations under the Medicaid Rebate Program.[11] Cf., *e.g.*, *United States ex rel. Roberts* v. *Aging*

[11] The government's pursuit of an FCA action reflects its conclusion, in coordination with HHS, that a manufacturer's calculations violate the Medicaid rebate framework, and it is thus consistent with Congress's intent that HHS should have the initial opportunity to determine manufacturers' obligations. The government's initial determination in bringing the suit is of course subject to judicial adjudication, in that whether the government will prevail on its fraud claims in court "ultimately" depends on "judicial interpretation," U.S. Br. in Opp. to Mot. to Dismiss, *United States ex rel. Kieff* v. *Wyeth*, 03-cv-12366, Docket entry No. 141 at 37 (D. Mass. Dec. 11, 2009), with deference to administrative interpretation of relevant statutory and regulatory provisions. This familiar judicial role in enforcement actions brought by the United States, subject to the checks imposed by prosecutorial discretion, in no

Care Home Health, Inc., 474 F. Supp. 2d 810, 820-821 (W.D. La. 2007) (unjust-enrichment claim to enforce Medicare provider's statutory obligations). On the 340B side, in addition to the enforcement measures provided by the PPA and the informal dispute resolution process, HRSA may terminate a manufacturer's participation in the 340B program.[12] 42 U.S.C. 1396r-8(b)(4)(B)(v); see Pet. App. 171a, 174a; 61 Fed. Reg. at 65,411-65,412. Congress's creation of these remedies for various violations by manufacturers of their statutory accurate-reporting and pricing obligations, and its failure to create any private enforcement mechanism for 340B rights, indicates that covered entities may not bypass the scheme of government enforcement by relying on purported contractual rights.

Respondent advances two primary arguments against this conclusion, neither of which is persuasive. First, respondent contends that HHS has previously indicated that, in its view, the 340B enforcement scheme does not place enforcement authority "either preliminarily or exclusively within the agency." Br. in Opp. 26. Respondent relies on HHS's responses to comments

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way suggests that the 340B Program allows for private suits by thousands of covered entities.

[12] Respondent contends that HRSA lacks effective enforcement authority because the termination sanction is too extreme to be a realistic option. Br. in Opp. 28-30. As discussed above, however, the PPACA gives HRSA additional enforcement tools. Respondent's argument also overlooks the fact that the primary conduct of which it complains—petitioners' alleged failure to comply with the accurate-reporting requirements of the Medicaid Rebate Program—can be investigated and remedied by CMS, see 42 U.S.C. 1396r-8(b)(3)(C), or prosecuted under other available civil or criminal statutes.

regarding its informal dispute resolution procedure, in which HHS stated that while "[n]o manufacturer or covered entity is required to avail itself of this process before resorting to other available measures," HHS expected that "parties" would "utilize the process before resorting to other remedies which may be available under applicable principles of law." 61 Fed. Reg. at 65,411-65,412. These statements do not purport to express a view regarding whether covered entities might be able to pursue other remedies for overcharges, and if so, what those remedies might be. Nor does HHS's description of the informal dispute resolution procedure as voluntary and not preclusive of other potential actions speak to whether the *PPA* confers enforceable rights on covered entities, or whether the combined Medicaid Rebate and 340B statutory schemes weigh against so construing the PPA.

Second, respondent contends that HHS's enforcement authority and its exercise of that authority have been inadequate. Respondent relies on government investigations that found that 340B entities had sometimes been overcharged, and recommended improvements in HRSA's oversight practices.[13] See *2005 Report* 10-15; *Oversight Report* 9-10. Respondent's view that HRSA should have more rigorously enforced manufacturer compliance, however, does not alter the fact that Congress centralized enforcement in the government, and that construing the PPA as respondent urges would be inconsistent with that intent.

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[13] HRSA has implemented many improvements in response. See, *e.g.*, *Oversight Report* 9-10, 12.

In any event, in the PPACA Congress confirmed its desire to keep enforcement authority in the government by directing HRSA to create a formal dispute resolution procedure, institute refund and civil penalty systems, and perform audits of manufacturers. § 7102(a), 124 Stat. 823-827. It is notable that, in response to questions about the adequacy of HRSA's enforcement practices in the pre-PPACA system, Congress opted to strengthen and formalize HRSA's enforcement authority, rather than providing for a direct private right of action. See *ibid.* The PPACA thus obviates respondent's enforcement concerns going forward—covered entities may invoke the new adjudicative process to remedy any perceived overcharges—and confirms that the PPA should not be construed to permit respondent to bypass the statutory remedial scheme.

Congress's provision of these extensive administrative procedures in the Medicaid and 340B statutes, and its formalization and enhancement of these procedures in the PPACA, reflect its judgment that HHS, as the administrator of the Medicaid Rebate and 340B programs, is best positioned to determine manufacturers' obligations in the first instance. HHS's comprehensive regulations govern manufacturers' calculation of AMP and Best Price, and when a covered entity alleges, as does respondent, that 340B overcharges are in part the result of inaccurate AMP and Best Price calculations, HHS should have the opportunity to exercise its expert judgment as to the proper application of its regulations. See *Illinois Council*, 529 U.S. at 13.

Permitting covered entities to enforce manufacturers' obligations in individual contract suits would undermine HHS's ability to administer both the Medicaid Re-

bate and the 340B Programs. The interdependent nature of the two programs' requirements means that an adjudication of rights under one program must proceed with an eye towards any implications for the other. In addition, allowing third-party beneficiary claims could result in a flood of litigation by covered entities challenging various aspects of manufacturers' calculations of the AMP, Best Price and ceiling price of numerous drugs. HHS cannot reasonably participate in every suit that might be filed, and so the potential for conflicting obligations imposed by adjudication without the benefit of HHS's participation or expertise is quite high. This result would undermine HHS's own enforcement efforts and the government's fraud actions.[14] Cf. *Buckman Co.* v. *Plaintiff's Legal Comm.*, 531 U.S. 341, 350 (2001) (finding state-law "fraud-on-the-FDA claims" preempted based on the agency's "responsibility to police fraud

[14] Third-party beneficiary suits by covered entities are thus quite different from suits by States to enforce manufacturers' obligations under the Medicaid Rebate Program. In *In re Pharmaceutical Industry Average Wholesale Price Litigation*, 321 F. Supp. 2d 187 (D. Mass. 2004), for instance, the United States took the position that two States' state-law fraud suit based on Best Price figures was not preempted. As the government explained, the Medicaid Rebate Program, like Medicaid generally, is a "cooperative federal-state program," in which States make their own payments to manufacturers and therefore have "long played a role" in identifying and prosecuting fraud. Gov't Amicus Br. 6-9 & n.5, 01-cv-12257, Docket entry No. 743 (March 18, 2004). Such suits, in which the United States would play a cooperative role, do not present the danger of inconsistent judgments uninformed by HHS's expertise that covered-entity suits would. *Id.* at 16-17.

consistently with the Administration's judgment and objectives").[15]

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted.

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[15] The primary jurisdiction doctrine does not mitigate the concerns raised by allowing third-party beneficiary suits, because referral to HHS would depend on a case-by-case judicial determination, *United States* v. *Western Pac. R.R.*, 352 U.S. 59, 64 (1956), and could interfere with HHS's enforcement priorities.