

Syllabus

ASTRA USA, INC., ET AL. *v.* SANTA CLARA COUNTY,
CALIFORNIACERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR
THE NINTH CIRCUIT

No. 09–1273. Argued January 19, 2011—Decided March 29, 2011

Section 340B of the Public Health Services Act imposes ceilings on prices drug manufacturers may charge for medications sold to specified health-care facilities (340B or covered entities), dominantly, local providers of medical care for the poor. The § 340B ceiling-price program (340B Program) is superintended by the Health Resources and Services Administration (HRSA), part of the Department of Health and Human Services (HHS). It is tied to the earlier-enacted, much larger Medicaid Drug Rebate Program, under which manufacturers gain Medicaid coverage for their drugs. To qualify for participation in this program, a manufacturer must enter into a standardized agreement with HHS undertaking to provide rebates to States on their Medicaid drug purchases. The amount of the rebates depends on a manufacturer’s “average” and “best” prices, as defined by legislation and regulation. The 340B Program, like the Medicaid Rebate Program, uses a form contract as an opt-in mechanism. The 340B Program also draws on the larger scheme’s pricing methodology. In the 340B Program’s contract, called the Pharmaceutical Pricing Agreement (PPA), manufacturers agree to charge covered entities no more than predetermined ceiling prices, derived from the “average” and “best” prices and rebates calculated under the Medicaid Rebate Program.

HRSA may require a manufacturer who overcharges a covered entity to reimburse that entity. HRSA may also terminate the manufacturer’s PPA, which terminates as well the manufacturer’s eligibility for Medicaid coverage of its drugs. Currently, HRSA handles overcharge complaints through informal procedures, but the 2010 Patient Protection and Affordable Care Act (PPACA) directs the Secretary to develop formal procedures. Once those procedures are in place, HRSA will reach an “administrative resolution,” which will be subject to judicial review under the Administrative Procedure Act (APA). In addition to authorizing compensation awards to overcharged entities, the PPACA provides for the imposition of monetary penalties payable to the Government.

Respondent Santa Clara County (County), operator of several 340B entities, filed suit against Astra and eight other pharmaceutical compa-

Syllabus

nies, alleging that they were overcharging 340B entities in violation of the PPAs. Asserting that 340B entities are the PPAs' intended beneficiaries, the County sought compensatory damages for breach of contract. The District Court dismissed the complaint, concluding that the PPAs conferred no enforceable rights on 340B entities. Reversing, the Ninth Circuit held that, while 340B entities have no right to sue under the statute, they could proceed against drug manufacturers as third-party beneficiaries of the PPAs.

Held: Suits by 340B entities to enforce ceiling-price contracts running between drug manufacturers and the Secretary of HHS are incompatible with the statutory regime. As the County has conceded, covered entities have no right of action under §340B itself. Congress vested authority to oversee compliance with the 340B Program in HHS and assigned no auxiliary enforcement role to covered entities. Nonetheless, the County maintains that the PPAs are contracts enforceable by covered entities as third-party beneficiaries. This argument overlooks that the PPAs simply incorporate statutory obligations and record the manufacturers' agreement to abide by them. The agreements have no negotiable terms. Like the Medicaid Rebate Program agreements, the PPAs provide the means by which drug manufacturers opt into the statutory scheme. A third-party suit to enforce an HHS-drug manufacturer agreement, therefore, is in essence a suit to enforce the statute itself. Telling in this regard, the County based its suit on allegations that the manufacturers charged more than the §340B ceiling price, not that they violated an independent substantive obligation arising from the PPAs.

The Ninth Circuit reasoned that suits like the County's would spread the enforcement burden instead of placing it entirely on the Government. But spreading the enforcement burden is hardly what Congress contemplated when it made HHS administrator of the interdependent Medicaid Rebate Program and 340B Program. Suits by 340B entities would undermine the agency's efforts to administer these two programs harmoniously and uniformly. Notably, the Medicaid Rebate Program's statute prohibits HHS from disclosing pricing information that could reveal the prices a manufacturer charges for its drugs. Had Congress meant to leave open the prospect of third-party beneficiary suits by 340B entities, it likely would not have barred them from obtaining the very information necessary to determine whether their asserted rights have been violated.

The Ninth Circuit noted that HHS's Office of the Inspector General has reported on HRSA's inadequate enforcement authority. But Congress did not respond to the reports of lax enforcement by inviting 340B entities to launch lawsuits. Instead, Congress opted to strengthen and

Syllabus

formalize HRSA's enforcement authority, to make the new adjudicative framework the proper remedy for covered entities' complaints, and to render the agency's resolution of those complaints binding, subject to judicial review under the APA. Pp. 117–122.

588 F. 3d 1237, reversed.

GINSBURG, J., delivered the opinion of the Court, in which all other Members joined, except KAGAN, J., who took no part in the consideration or decision of the case.

Lisa S. Blatt argued the cause for petitioners. With her on the briefs were *Jeffrey L. Handwerker, Anthony J. Franze, James P. Muehlberger, Robert J. McCully, Ina D. Chang, Paul J. Riehle, Lyndon M. Tretter, Richard D. Raskin, Scott D. Stein, Kirke M. Hasson, Brian W. Shaffer, Jennifer Beth Jordan, R. Ted Cruz, Allyson N. Ho, Peter N. Larson, Fletcher C. Alford, and Kelly J. Davidson.*

Ginger D. Anders argued the cause for the United States as *amicus curiae* in support of petitioners. With her on the brief were *Acting Solicitor General Katyal, Assistant Attorney General West, Deputy Solicitor General Kneedler, Michael S. Raab, Benjamin M. Shultz, Janice L. Hoffman, and Mark D. Polston.*

David C. Frederick argued the cause for respondent. With him on the brief were *Scott H. Angstreich, Scott K. Attaway, Greta S. Hansen, Juniper L. Downs, Sanford Svetcov, Jeffrey W. Lawrence, Susan K. Alexander, and Aelish M. Baig.**

*Briefs of *amici curiae* urging reversal were filed for the Chamber of Commerce of the United States of America by *Kannon K. Shanmugam* and *Robin S. Conrad*; for the Pharmaceutical Research and Manufacturers of America by *Paul D. Clement* and *Jeffrey S. Bucholtz*; and for the Washington Legal Foundation by *Daniel J. Popeo* and *Richard A. Samp.*

Briefs of *amici curiae* urging affirmance were filed for the State of Kansas et al. by *Steve Six*, Attorney General of Kansas, and *Stephen R. McAllister*, Solicitor General, and by the Attorneys General for their respective jurisdictions as follows: *Terry Goddard* of Arizona, *Peter J. Nickles* of the District of Columbia, *Chris Koster* of Missouri, and *Darrell V. McGraw, Jr.*, of West Virginia; for AARP et al. by *Rochelle Bobroff, Stacy*

Opinion of the Court

JUSTICE GINSBURG delivered the opinion of the Court.

Section 340B of the Public Health Services Act, 42 U. S. C. § 256b (2006 ed. and Supp. IV), imposes ceilings on prices drug manufacturers may charge for medications sold to specified health-care facilities. Those facilities, here called “340B” or “covered” entities, include public hospitals and community health centers, many of them providers of safety-net services to the poor. The § 340B ceiling-price program (340B Program) is superintended by the Health Resources and Services Administration (HRSA), a unit of the Department of Health and Human Services (HHS). Drug manufacturers opt into the 340B Program by signing a form Pharmaceutical Pricing Agreement (PPA) used nationwide. PPAs are not transactional, bargained-for contracts. They are uniform agreements that recite the responsibilities § 340B imposes, respectively, on drug manufacturers and the Secretary of HHS. Manufacturers’ eligibility to participate in State Medicaid programs is conditioned on their entry into PPAs for covered drugs purchased by 340B entities.

It is conceded that Congress authorized no private right of action under § 340B for covered entities who claim they have been charged prices exceeding the statutory ceiling. This case presents the question whether 340B entities, though accorded no right to sue for overcharges under the statute itself, may nonetheless sue allegedly overcharging manufacturers as third-party beneficiaries of the PPAs to which the manufacturers subscribed. We hold that suits by 340B entities to enforce ceiling-price contracts running between drug manufacturers and the Secretary of HHS are incompatible with the statutory regime.

Canan, and *Michael Schuster*; for A Coalition of 340B Entity Groups by *Joel M. Hamme*; for Contract Law Professors by *Stephen M. Tillery*; and for Federal Courts Professors by *Michael J. Brickman*, *James C. Bradley*, *Nina H. Fields*, and *Lumen N. Mulligan*.

Lawrence J. Joseph filed a brief for APA Watch as *amicus curiae*.

Opinion of the Court

Congress placed the Secretary (acting through her designate, HRSA) in control of § 340B's drug-price prescriptions. That control could not be maintained were potentially thousands of covered entities permitted to bring suits alleging errors in manufacturers' price calculations. If 340B entities may not sue under the statute, it would make scant sense to allow them to sue on a form contract implementing the statute, setting out terms identical to those contained in the statute. Though labeled differently, suits to enforce § 340B and suits to enforce PPAs are in substance one and the same. Their treatment, therefore, must be the same, "[n]o matter the clothing in which [340B entities] dress their claims." *Tenet v. Doe*, 544 U. S. 1, 8 (2005).

I

A

The 340B Program is tied to the earlier-enacted, much larger Medicaid Drug Rebate Program. Adopted by Congress in 1990, the Medicaid Rebate Program covers a significant portion of drug purchases in the United States. See GAO, J. Dicken, Prescription Drugs: Oversight of Drug Pricing in Federal Programs 1 (GAO-07-481T, 2007) (testimony before the Committee on Oversight and Government Reform, House of Representatives).¹ To gain payment under Medicaid for covered drugs, a manufacturer must enter a standardized agreement with HHS; in the agreement, the manufacturer undertakes to provide rebates to States on their Medicaid drug purchases. 104 Stat. 1388-143, as amended, 124 Stat. 3290, 42 U.S.C. § 1396r-8(a). The amount of the rebates depends on the manufacturer's "aver-

¹ "In 2004, Medicaid . . . prescription drug spending reached \$31 billion," GAO, J. Dicken, Prescription Drugs: Oversight of Drug Pricing in Federal Programs 4 (GAO-07-481T, 2007) (testimony before the Committee on Oversight and Government Reform, House of Representatives), while in 2003, 340B entities "spent an estimated \$3.4 billion on drugs," *id.*, at 5.

Opinion of the Court

age” and “best” prices, as defined by legislation and regulation. § 1396r–8(c), (k).

Calculation of a manufacturer’s “average” and “best” prices, undertaken by the pharmaceutical company, is a complex enterprise requiring recourse to detailed information about the company’s sales and pricing. § 1396r–8(k); 42 CFR § 447.500–520 (2010). To enable HHS to calculate the rebate rate for each drug, manufacturers submit the relevant data to HHS on a quarterly basis. § 1396r–8(b)(3). With exceptions set out in the legislation, HHS is prohibited from disclosing the submitted information “in a form which discloses the identity of a specific manufacturer . . . [or] prices charged for drugs by such manufacturer.” § 1396r–8(b)(3)(D).

Under § 340B, added in 1992, 106 Stat. 4967, as amended, 124 Stat. 823, manufacturers participating in Medicaid must offer discounted drugs to covered entities, dominantly, local facilities that provide medical care for the poor. See § 256b(a); § 1396r–8(a)(1) (2006 ed.). The 340B Program, like the Medicaid Drug Rebate Program, employs a form contract as an opt-in mechanism. The 340B Program also draws on the larger scheme’s pricing methodology. In their 340B Program contracts with HHS, called Pharmaceutical Pricing Agreements (PPAs), see *supra*, at 113, manufacturers agree to charge covered entities no more than predetermined ceiling prices, derived from the “average” and “best” prices and rebates calculated under the Medicaid Drug Rebate Program. § 256b(a)(1) (2006 ed., Supp. IV); see App. to Pet. for Cert. 165a–171a (PPA § I–II).²

If a manufacturer overcharges a covered entity, HRSA may require the manufacturer to reimburse the covered entity; HRSA may also terminate the manufacturer’s PPA,

² The 340B Program also covers over-the-counter medications for which there are no Medicaid rebates. 42 U.S.C. § 256b(a)(2)(B) (2006 ed. and Supp. IV). For such drugs, § 340B prescribes a substitute calculation method. § 256b(a)(2)(B)(i).

Opinion of the Court

§ 1396r-8(b)(4)(B)(i), (v) (2006 ed.); App. to Pet. for Cert. 174a (PPA § IV(c)), which terminates as well the manufacturer's eligibility for Medicaid coverage of its drugs, § 1396r-8(a)(1), (5). Currently, HRSA handles overcharge complaints through informal procedures. Manufacturer Audit Guidelines and Dispute Resolution Process, 61 Fed. Reg. 65412 (1996). The 2010 Patient Protection and Affordable Care Act (PPACA), Pub. L. 111-148, 124 Stat. 119, provides for more rigorous enforcement. The PPACA directs the Secretary to develop formal procedures for resolving overcharge claims. *Id.*, at 826, 42 U.S.C. § 256b(d)(3)(A) (2006 ed., Supp. IV). Under those procedures, which are not yet in place, HRSA will reach an "administrative resolution" that is subject to judicial review under the Administrative Procedure Act (APA), 5 U.S.C. § 701 *et seq.* See 124 Stat. 827, 42 U.S.C. § 256b(d)(3)(C). In addition to authorizing compensation awards to overcharged entities, the PPACA provides for the imposition of monetary penalties payable to the Government. *Id.*, at 824-825, 42 U.S.C. § 256b(d)(1)(B)(ii), (vi).

B

Respondent Santa Clara County (County), operator of several 340B entities, commenced suit against Astra and eight other pharmaceutical companies, alleging that the companies were overcharging 340B health-care facilities in violation of the PPAs to which the companies subscribed. The County styled its suit a class action on behalf of both 340B entities in California and the counties that fund those entities. Asserting that the 340B entities and the counties that fund them are the intended beneficiaries of the PPAs, the County sought compensatory damages for the pharmaceutical companies' breach of contract.

The District Court dismissed the complaint, concluding that the PPAs conferred no enforceable rights on 340B entities. Reversing the District Court's judgment, the Ninth Circuit held that covered entities, although they have no

Opinion of the Court

right to sue under the statute, could maintain the action as third-party beneficiaries of the PPAs. 588 F. 3d 1237, 1241 (2009).

We granted certiorari, 561 U. S. 1057 (2010),³ and now reverse the Ninth Circuit’s judgment.

II

As the County conceded below and before this Court, see 588 F. 3d, at 1249; Tr. of Oral Arg. 45, covered entities have no right of action under § 340B itself. “[R]ecognition of any private right of action for violating a federal statute,” currently governing decisions instruct, “must ultimately rest on congressional intent to provide a private remedy.” *Virginia Bankshares, Inc. v. Sandberg*, 501 U. S. 1083, 1102 (1991). See also *Stoneridge Investment Partners, LLC v. Scientific-Atlanta, Inc.*, 552 U. S. 148, 164 (2008); *Alexander v. Sandoval*, 532 U. S. 275, 286 (2001). Congress vested authority to oversee compliance with the 340B Program in HHS and assigned no auxiliary enforcement role to covered entities.

Notwithstanding its inability to assert a statutory right of action, the County maintains that the PPAs implementing the 340B Program are agreements enforceable by covered entities as third-party beneficiaries. A nonparty becomes legally entitled to a benefit promised in a contract, the County recognizes, only if the contracting parties so intend. Brief for Respondent 31 (citing Restatement (Second) of Contracts § 302(1)(b) (1979)). The PPAs “specifically

³ U. S. Courts of Appeals have divided on the circumstances under which suits may be brought by alleged third-party beneficiaries of Government contracts. Compare 588 F. 3d 1237, 1244 (CA9 2009) (case below) (“Any intended beneficiary has the right to enforce the obligor’s duty of performance . . .”), with *Grochowski v. Phoenix Construction*, 318 F. 3d 80, 85–86 (CA2 2003) (“there is no presumption in favor of a right to bring suit” as third-party beneficiary of a government contract), and *Dewakuku v. Martinez*, 271 F. 3d 1031, 1042 (CA Fed. 2001) (rejecting third-party suit).

Opinion of the Court

nam[e]” covered entities as the recipients of discounted drugs, the County observes; indeed the very object of the agreements is to ensure that those entities would be “charge[d] . . . no more than the ceiling price.” Brief for Respondent 33. When the Government uses a contract to secure a benefit, the County urges, the intended recipient acquires a right to the benefit enforceable under federal common law. *Id.*, at 30. But see 9 J. Murray, Corbin on Contracts § 45.6, p. 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.”).

The County’s argument overlooks that the PPAs simply incorporate statutory obligations and record the manufacturers’ agreement to abide by them. The form agreements, composed by HHS, contain no negotiable terms. Like the Medicaid Drug Rebate Program agreements, see *supra*, at 114–115, the 340B Program agreements serve as the means by which drug manufacturers opt into the statutory scheme. A third-party suit to enforce an HHS-drug manufacturer agreement, therefore, is in essence a suit to enforce the statute itself. The absence of a private right to enforce the statutory ceiling-price obligations would be rendered meaningless if 340B entities could overcome that obstacle by suing to enforce the contract’s ceiling-price obligations instead. The statutory and contractual obligations, in short, are one and the same. See *Grochowski v. Phoenix Construction*, 318 F. 3d 80, 86 (CA2 2003) (when a government contract confirms a statutory obligation, “a third-party private contract action [to enforce that obligation] would be inconsistent with . . . the legislative scheme . . . to the same extent as would a cause of action directly under the statute” (internal quotation marks omitted)).

Telling in this regard, the County based its suit on allegations that the manufacturers charged more than the § 340B ceiling price, see, *e.g.*, Third Amended Complaint

Opinion of the Court

in No. 3:05-cv-03740 (ND Cal.), ¶¶ 1, 65, not that they violated any independent substantive obligation arising only from the PPAs.⁴ Repeatedly, the County acknowledged that § 340B is the source of the contractual term allegedly breached. See, *e. g.*, *id.*, ¶ 28 (“[Section] 340B requires pharmaceutical manufacturers to ensure that § 340B Participants pay no more than the ‘ceiling price’ . . . for any pharmaceutical product.”); *id.*, ¶ 36 (“Under both § 340B and the PPA, [drug manufacturers] are required to ensure that the § 340B Participants . . . pay no more for any product than the § 340B ceiling price.”).

The Ninth Circuit determined that “[p]ermitting covered entities to sue as intended beneficiaries of the PPA is . . . wholly compatible with the Section 340B program’s objectives” to ensure “that drug companies comply with their obligations under the program and provide [the required] discounts.” 588 F. 3d, at 1251. Suits like the County’s, the Court of Appeals reasoned, would spread the enforcement burden instead of placing it “[e]ntirely] on the government.” *Ibid.* (citing *Price v. Pierce*, 823 F. 2d 1114, 1121 (CA7 1987)). But spreading the enforcement burden, the United States stressed, both in the Ninth Circuit and in this Court, is hardly what Congress contemplated when it “centralized enforcement in the government.” Brief for United States as *Amicus Curiae* 32; see Brief for United States as *Amicus Curiae* in No. 09–15216 (CA9), p. 13 (County’s challenge is at

⁴ Whether a contracting agency may authorize third-party suits to enforce a Government contract is not at issue in this case. Cf. Brief for United States as *Amicus Curiae* 22. We can infer no such authorization where a contract simply incorporates statutorily required terms and otherwise fails to demonstrate any intent to allow beneficiaries to enforce those terms. Permitting such a suit, it is evident, would “allo[w] third parties to circumvent Congress’s decision not to permit private enforcement of the statute.” *Id.*, at 23–24; cf. Brief for United States as *Amicus Curiae* in No. 09–15216 (CA9), p. 21 (“In drafting and entering into [PPAs], HHS never imagined that a 340B entity could bring a third-party beneficiary lawsuit like [the County]’s.”).

Opinion of the Court

odds with Congress' unitary administrative and enforcement scheme).⁵

Congress made HHS administrator of both the Medicaid Drug Rebate Program and the 340B Program, the United States observed, Brief for United States as *Amicus Curiae* 33–34, and “[t]he 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,” *id.*, at 34. Far from assisting HHS, suits by 340B entities would undermine the agency’s efforts to administer both Medicaid and §340B harmoniously and on a uniform, nationwide basis.⁶ Recognizing the County’s right to proceed in court could spawn a multitude of dispersed and uncoordinated lawsuits by 340B entities. With HHS unable to hold the control rein, the risk of conflicting adjudications would be substantial.

⁵The County notes that in *In re Pharmaceutical Industry Average Wholesale Price Litigation*, 263 F. Supp. 2d 172 (Mass. 2003), the United States urged that the statute establishing the Medicaid Drug Rebate Program, §1396r–8, does not preempt States from maintaining state-law fraud claims based on fraudulent reporting of “best prices” to HHS. Brief for Respondent 22–23. See Brief for United States as *Amicus Curiae* in No. 1:01–cv–12257 (D Mass.), pp. 6–9 (observing that States make their own payments to manufacturers and have long played a role in identifying and prosecuting Medicaid fraud). We take no position on this issue.

⁶Because the Ninth Circuit focused on the 340B Program in isolation, it failed to recognize that the interests of States under the Medicaid Drug Rebate Program and covered entities under the 340B Program may conflict. For example, “average” prices are used both to set the amount manufacturers must pay in Medicaid rebates and to establish §340B ceiling prices. §1396r–8(c); §256b(a)(1). Typically, the lower the “average” price, the lower a product’s price to a 340B entity. Brief for United States as *Amicus Curiae* in No. 09–15216, p. 31. But the higher the “average” price, the more a State Medicaid agency typically receives in rebates from the manufacturers. *Ibid.* HHS can use its expertise to ascertain and balance the competing interests. *Id.*, at 31–32. Courts as first-line decisionmakers are not similarly equipped to deal with the whole picture.

Opinion of the Court

As earlier noted, see *supra*, at 115, the Medicaid Rebate Program’s statute prohibits HHS from disclosing pricing information in a form that could reveal the prices a manufacturer charges for drugs it produces. § 1396r–8(b)(3)(D).⁷ This ban on disclosure is a further indication of the incompatibility of private suits with the statute Congress enacted. If Congress meant to leave open the prospect of third-party beneficiary suits by 340B entities, it likely would not have barred the potential suitors from obtaining the very information necessary to determine whether their asserted rights have been violated.⁸

It is true, as the Ninth Circuit observed, that HHS’s Office of the Inspector General (OIG) has published reports finding that “HRSA lacks the oversight mechanisms and authority to ensure that [covered] entities pay at or below the . . . ceiling price.” 588 F. 3d, at 1242 (quoting OIG, D. Levinson, Deficiencies in the Oversight of the 340B Drug Pricing Program, p. ii (OEI–05–02–00072, Oct. 2005)). See also 588 F. 3d, at 1242–1243 (citing OIG, D. Levinson, Review of 340B Prices 11 (OEI–05–02–00073, July 2006) (estimating that covered entities overpaid \$3.9 million in June 2005 alone)). But Congress did not respond to the reports of inadequate HRSA enforcement by inviting 340B entities to launch lawsuits in district courts across the country. Instead, in the PPACA, Congress directed HRSA to create a formal dispute resolution procedure, institute refund and civil penalty systems, and perform audits of manufacturers. 124 Stat. 823–827, 42 U. S. C. § 256b(d). Congress thus opted to strengthen and

⁷ HHS interprets this provision, the United States informs us, as prohibiting the agency from disclosing to covered entities the ceiling prices calculated based on information submitted by the manufacturers. Brief for United States as *Amicus Curiae* 28.

⁸ Going forward, the 2010 Patient Protection and Affordable Care Act, Pub. L. 111–148, 124 Stat. 119, in conjunction with the new administrative adjudication process directed by the Act, will require HHS to give covered entities access to some of the information submitted by manufacturers. *Id.*, at 826, 42 U. S. C. § 256b(d)(3)(B)(iii).

Opinion of the Court

formalize HRSA's enforcement authority, to make the new adjudicative framework the proper remedy for covered entities complaining of "overcharges and other violations of the discounted pricing requirements," *id.*, at 823, 42 U.S.C. § 256b(d)(1)(A), and to render the agency's resolution of covered entities' complaints binding, subject to judicial review under the APA, *id.*, at 827, 42 U.S.C. § 256b(d)(3)(C).

* * *

For the reasons stated, the judgment of the U. S. Court of Appeals for the Ninth Circuit is

Reversed.

JUSTICE KAGAN took no part in the consideration or decision of this case.