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NOTE: Where it is feasible, a syllabus (headnote) will be released, as is being done in connection with this case, at the time the opinion is issued. The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See *United States* v. *Detroit Timber & Lumber Co.,* 200 U. S. 321, 337.

SUPREME COURT OF THE UNITED STATES

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ASTRA USA, INC., ET AL. *v.* SANTA CLARA COUNTY, CALIFORNIA

CERTIORARI 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 Secre-

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tary 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 companies, 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-

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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 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. 5–10.

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.