No. 09-1273

IN THE

# Supreme Court of the United States

ASTRA USA, INC., *et al.*,
*Petitioners*,

v.

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

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

## REPLY BRIEF

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## REPLY BRIEF

Respondent seeks what the 340B Act indisputably fails to provide it: a cause of action. Whether this suit is framed as a breach of contract action under federal common law or an implied right of action under the statute, the substantive right respondent asserts and the private remedy it seeks are one and the same.

Abandoning the argument made below and the Ninth Circuit's rationale, respondent concedes that congressional intent—and not the parties' intent as interpreted under the common law—is the relevant touchstone for whether covered entities have a

private right to enforce a manufacturer's obligations under the 340B Act. Respondent also concedes that the Act does not confer an express or implied right of action under this Court's precedents including *Gonzaga University v. Doe*, 536 U.S. 273 (2002), and *Alexander v. Sandoval*, 532 U.S. 275 (2001). Resp. Br. 17 n.41, 36-38. Those concessions bring this case to an end. If Congress did not intend 340B entities to enforce a manufacturer's ceiling price obligations under the Act itself, then Congress did not intend to allow those entities to enforce those same obligations anyway under the rubric of federal common law.

The feature of an "agreement" between the Secretary of Health and Human Services ("the Secretary") and manufacturers, 42 U.S.C. § 256b(a)(1), does not authorize common law suits by 340B entities. That statutory "agreement" imposes ceiling price obligations on manufacturers that (1) run explicitly only to the Secretary as the other party to the agreement; (2) are based on information that is confidential and cannot be disclosed by the Secretary; and (3) are accompanied by specific rights that manufacturers have against covered entities but without any corresponding rights running in favor of covered entities. Congress moreover empowered the Secretary, who administers both the 340B program and the interrelated and much larger Medicaid Rebate program, to resolve the multitude of complexities and ambiguities in pricing methodology, to balance the potentially conflicting objectives between the two programs, and to audit and impose penalties to ensure compliance with both Acts.

Just like suits under an implied right of action, suits under the common law by more than 14,500 covered entities to challenge hundreds of thousands,

if not millions, of pricing transactions for all drugs covered by Medicaid would seriously disrupt that scheme. Such suits would also conflict with the flexibility that the Secretary has conferred on manufacturers to make reasonable assumptions in calculating Average Manufacturer Price ("AMP") and Best Price ("BP").

Allowing third parties to enforce the Act under federal common law would eviscerate the principles of *Gonzaga*, *Sandoval*, and decades of similar precedent and supplant them with a rule that would presumptively confer enforceable rights on all purported beneficiaries of federal public welfare programs administered through contracts. That regime would illegitimately expand the Article III power of the judiciary to invent through the back door what Congress declined to allow through the front door.

### A. Common Law Suits Would Circumvent The Absence Of A Private Right Of Action

1. Respondent argues that Congress mandated the Pharmaceutical Pricing Agreement ("PPA") against a background common law rule that permits certain third-party beneficiaries to sue to enforce an agreement. Resp. Br. 30-36. But if that rule governs, respondent loses. Respondent disavows the rule under common law, *id*. at 22, 47-48, presumably because it would require respondent to make the counter-factual showing that the Secretary and petitioners intended to confer enforceable rights on covered entities. *See* Restatement (Second) of Contracts § 302(1) (1981) ("[A] beneficiary of a promise is an intended beneficiary if recognition of a right . . . is appropriate to effectuate the *intention of the parties*.") (emphasis added); *id*. § 304 cmt. b ("[T]he parties to a contract have the power, *if they*

*so intend*, to create a right in a third person.") (emphasis added).

Respondent thus repeatedly asks this Court to ignore the Secretary's intent *not* to confer enforceable rights in the PPA. Resp. Br. 22, 47-48. Respondent contends that it could enforce the PPA under federal common law even if the PPA had *expressly* precluded suits by covered entities. *Id*. at 47. *But see* Restatement (Second) of Contracts § 302(1) (promisor and promisee may agree to preclude third party rights). Respondent recognizes that, because the manufacturers' obligation to charge prices no higher than the 340B ceiling price derives *in haec verba* from the 340B Act, respondent must show that *Congress* intended to create a cause of action in favor of 340B entities. Resp. Br. 22, 37, 47-48. But if congressional intent is the definitive guidepost, this Court should not accept anything less than that required by *Gonzaga* and similar cases.

In *Gonzaga*, this Court rejected a university student's attempts to enforce the private remedy expressly granted under 42 U.S.C. § 1983 against Gonzaga University for allegedly violating the Family Educational Rights and Privacy Act ("FERPA"), 20 U.S.C. § 1232g. This Court held that the student could not satisfy the requirements of a § 1983 claim because FERPA did not "unambiguously" and with "explicit rights-creating" language create a private remedy in favor of students. *Gonzaga*, 536 U.S. at 283, 284, 287. The fact that FERPA benefitted the student was insufficient. *Id*. at 282, 284-85. Other decisions similarly have made clear that "[t]he question is not simply who would benefit from the Act, but whether Congress intended to confer federal rights upon those beneficiaries." *California v.*

*Sierra Club*, 451 U.S. 287, 294 (1981); *accord Univs. Research Ass'n, Inc. v. Coutu*, 450 U.S. 754, 771-72 (1981).

Congress did not, under those standards, authorize 340B entities to enforce the Act's drug pricing provisions. Congress authorized the Secretary to enforce those provisions. The 340B Act confers only one private remedy: drug manufacturers have a right to damages for a 340B entity's violation of the Act. 42 U.S.C. § 256b(a)(5)(D). By contrast, Congress provided no private remedy in favor of 340B entities allegedly injured by a manufacturer's pricing calculations. Moreover, the Act gives manufacturers audit rights to ensure 340B entities' compliance with the Act. *Id.* § 256b(a)(5)(C). The Act gives no similar right to 340B entities to audit a manufacturer's pricing calculations. *Cf. Touche Ross & Co. v. Redington*, 442 U.S. 560, 572 (1979) ("[W]hen Congress wished to provide a private damages remedy, it knew how to do so and did so expressly.").

The Act in fact contemplates that 340B entities are barred from second-guessing a manufacturer's AMP and BP calculations. Drug pricing information is "confidential," and the Secretary may not disclose underlying pricing data. 42 U.S.C. § 1396r-8(b)(3)(D). Yet this suit seeks an astonishingly massive and unwieldy audit of petitioners' AMP and BP calculations that comprise over $100 billion annually in drug sales. Pet. Br. 39-40; Resp. Br. 14 n.39. That scheme conflicts with what Congress, the Secretary, and drug manufacturers intended when the parties entered into the PPA.

The Court's analysis in *United States v. Erika, Inc.*, 456 U.S. 201 (1982), similarly precludes respondent from evading the absence of a right of action under the 340B Act by framing the same claim as a breach of contract. In *Erika*, Congress implemented the Medicare Act through contracts between the government and insurance carriers. The Court rejected the notion that a purported beneficiary under the Act could bring a third-party breach of contract claim to assert a right he could not bring under the Act itself. *Id*. at 211 & n.14.

Respondent dismisses *Erika* on the ground that "[n]either § 256b nor the Agreement contains any comparable provision that could preclude 340B entities from enforcing their rights as intended third-party beneficiaries." Resp. Br. 40. But the Act in *Erika* contained no provision precluding the purported beneficiary from suing. The Court nonetheless held that the statute's implicit preclusion of such a right is read into the contract. *Erika*, 456 U.S. at 211 n.14. By parity of reasoning, the preclusion of judicially enforceable rights under the 340B Act is a necessary component of the PPA.

Respondent also argues that its third-party beneficiary breach of contract suit does not circumvent the absence of an implied right of action because the latter might give covered entities the right to sue a manufacturer for refusing to sign a PPA when the manufacturer's drugs are covered by Medicaid. Resp. Br. 38. Even accepting that hypothesis, respondent's breach of contract suit to enforce the PPA's ceiling price obligations is substantively indistinguishable from an implied right of action to enforce those same obligations in the 340B Act. Both suits seek to enforce the same right and to obtain the same

remedy. Common law suits also would cause the same programmatic disruptions that Congress evidently sought to prevent when it concededly declined under the Act to provide for a private right to sue.

The government suggests that an agency through a contract may confer rights to enforce an *in haec verba* statutory requirement if Congress has delegated such rights-granting authority to the agency. Br. for the United States as Amicus Curiae ("U.S. Br.") 23-24. That position, however, is hard to reconcile with *Sandoval*, where the Court assumed that Congress had empowered the agency to promulgate regulations prohibiting funding recipients from engaging in practices with a discriminatory effect. 532 U.S. at 281-83, 286. The Court nonetheless held that even a validly promulgated regulation may not be the source of a cause of action; a private remedy must stem directly from Congress. *Id*. at 286-87. In any event, the government correctly explains that the Secretary did not intend to confer rights on 340B entities under the PPA. U.S. Br. 21-25.

2. Respondent argues that this Court's private right of action precedents are irrelevant because the 340B Act imposes the ceiling price obligations "through actual contracts, rather than a Spending Clause mandate that is simply 'in the nature of a contract.'" Resp. Br. 37 n.45 (quoting *Barnes v. Gorman*, 536 U.S. 181, 186 (2002)). But the contract mechanism employed in the 340B Act reflects Congress's choice to adopt an opt-in program, *i.e.*, the ceiling price obligations become effective only if manufacturers convey their written consent in the PPA. That arrangement does not reflect Congress's intent to confer a common law remedy on purported

beneficiaries any more than had Congress imposed the same funding obligation by regulation with the party's implicit consent. *Sandoval*, 532 U.S. at 288-91. Requiring manufacturers' explicit consent to the ceiling price obligations does not authorize courts to invent a cause of action under federal common law or to impose unanticipated liabilities on manufacturers.

The lack of a common law remedy for 340B entities does not render the PPA "meaningless." Resp. Br. 21; *accord id.* at 37. As stated, the Act's drug ceiling price provisions do not apply to drug manufacturers unless they enter into the PPA with the Secretary. 42 U.S.C. § 256b(a)(1); *see also* Health Res. & Servs. Admin., 340B Database: Manufacturer, http://opanet.hrsa.gov/opamod/Manufacturers.aspx (listing "inactive" manufacturers without an effective PPA). There is also a historic explanation for why Congress implemented the 340B Act through the PPA. The 340B Act borrowed the contract mechanism of the Medicaid Rebate Act, 42 U.S.C. §§ 256b(a)(1), 1396r-8(c), and the Medicaid Rebate Act in turn built upon pre-existing contracts between States and manufacturers providing for rebates, *id*. § 1396r-8(a)(4). *See also* Resp. Br. 43.

Respondent also obliquely relies on Section 256b(a)(5)(D), which refers to an "agreement *between the entity and the manufacturer* under this paragraph." Resp. Br. 7 (emphasis added); *accord id.* at 20, 33, 47-48. When read in context, Congress presumably meant to refer to the Secretary rather than a covered entity. *Cf. U.S. Nat'l Bank of Or. v. Indep. Ins. Agents of Am., Inc.,* 508 U.S. 439, 462 (1993). Section 256b(a)(5)(D) provides that 340B entities that divert covered drugs or receive 340B

discounts that improperly trigger Medicaid drug rebates are liable to the manufacturer for an amount equal to the total discount provided to the entity under the PPA for the diverted or Medicaid-billed product. *See also* Veterans Health Care Act of 1992: Summary of Provisions, 138 Cong. Rec. S17867 (Oct. 8, 1992) (Act would render covered entity "liable to the manufacturer in an amount equal to the reduction in the price of the drug provided under the rebate or discount agreement *with the Secretary of HHS*.") (emphasis added).

Covered entities are not parties to the PPA, and respondent has never suggested otherwise. Indeed, the premise of this suit is respondent's status as a *non*-party to the PPA. It strains credulity that an ambiguous reference contained in a formula for calculating the amount of reimbursement owed to manufacturers confers on 340B entities enforceable rights and remedies. Congress "does not, one might say, hide elephants in mouseholes." *Whitman v. Am. Trucking Ass'ns, Inc.*, 531 U.S. 457, 468 (2001).

3. In respondent's view, "Congress's decision to implement § 256b through federal contracts . . . provides all the evidence of congressional intent necessary" to presumptively establish a cause of action under federal common law. Resp. Br. 40. That premise is backwards. Statutes conferring federal common law authority on courts do not confer rights-granting authority to enforce a federal statute. *Mertens v. Hewitt Assocs.*, 508 U.S. 248, 255 & n.5 (1993); *Texas Indus., Inc. v. Radcliff Materials, Inc.*, 451 U.S. 630, 643-46 (1981). Respondent's contrary view would transform the post-*Erie* precept that federal common law authority is exceedingly narrow and limited, Pet. Br. 42-44, into a rule that gives

federal courts expansive and free-wheeling power to trump the decision of Congress not to create a cause of action under a statute. *Cf. Sandoval*, 532 U.S. at 287 ("Having sworn off the habit of venturing beyond Congress's intent, we will not accept respondents' invitation to have one last drink.").

Respondent's proposed regime would seriously upset the expectations of government contractors and funding recipients that never anticipated that their contracts silently subjected them to class actions and potential sprawling lawsuits like this case. Pet. Br. 39-40; Br. of the Chamber of Commerce as Amicus Curiae 12-18. As discussed at the petition stage, this Court's modern implied right of action decisions have prompted enterprising lawyers to seek private enforcement of a statute by bringing a third-party breach of contract suit. Pet. 17-18. Respondent's proposal would pave the way for purported beneficiaries of numerous health care and other federal welfare statutes to bring common law suits seeking private enforcement of statutes that contain no implied right of action. Litigants already have begun to cite the decision below in seeking third-party beneficiary contract rights to enforce other government programs administered through contracts. *See, e.g.*, *Marques v. Wells Fargo Home Mortg., Inc.*, No. 09-cv-1985, 2010 WL 3212131 (S.D. Cal. Aug. 12, 2010) (Troubled Asset Relief Program ("TARP")).

### B. The Federal Nature Of The PPA Does Not Authorize A Common Law Cause Of Action

1. Respondent argues that *Jackson Transit Authority v. Local Division 1285*, 457 U.S. 15 (1982), and similar decisions establish that third-party beneficiaries of a federal contract may sue to enforce

the contract unless Congress affirmatively precludes such a suit. Resp. Br. 1, 19-20, 25-28, 36, 38. But none of those decisions so holds. Those cases resolve the question whether a breach of contract dispute between the parties to a contract should be resolved in a federal forum, rather than a state forum. *Jackson Transit* held that, although a federal statute contemplated future contracts between federal funding recipients and unions, Congress did not intend that disputes between the parties under such contracts be resolved in federal courts. 457 U.S. at 16, 29.

The other decisions relied upon by respondent, Resp. Br. 25-29, are to the same effect. *See Empire HealthChoice Assurance, Inc. v. McVeigh*, 547 U.S. 677, 693-99 (2006) (holding that contract-based claims between a federal employee insurance carrier and the insured arose under state law); *Norfolk & W. Ry. Co. v. Nemitz*, 404 U.S. 37, 44-45 (1991) (holding that suit between the parties to the federal contract arose under federal law). For similar reasons, respondent errs in faulting petitioners for not citing *International Association of Machinists v. Central Airlines, Inc.*, 372 U.S. 682 (1963), a case not cited by respondent until its merits brief. Resp. Br. 29. That decision merely holds that federal courts had subject matter jurisdiction to resolve a dispute between two parties to a contract mandated by federal law. *Central Airlines*, 372 U.S. at 691-96.

In *Miree v. DeKalb County*, 433 U.S. 25, 28 (1977), *see* Resp. Br. 32, the Court held that state law governed a third-party beneficiary claim to enforce a contract contemplated by an Act of Congress. *See also Boyle v. United Techs. Corp.*, 487 U.S. 500, 506-09 (1988) (discussing *Miree*). *Miree* did not address,

however, the validity of the third-party beneficiary claim or whether the Act at issue contained an implied right of action. 433 U.S. at 33-34. And in *American Surety Co. of New York v. Schultz*¸ 237 U.S. 159, 160 (1915), *see* Resp. Br. 25, the bond sued upon did not incorporate any requirement under a federal statute. Accordingly, this Court's decisions do not support the proposition that a non-party to a contract embodying a statutory requirement can bring suit to enforce that requirement absent showing an implied right of action under the statute.

2. Respondent relies on the Court's observation in *Jackson Transit* that the question presented in that case did "not fit comfortably in th[e] mold" of a private right of action case. Resp. Br. 1, 21, 36 (quoting *Jackson Transit*, 457 U.S. at 20). The Court in *Jackson Transit* explained that whether or not the statute there contained an implied right of action, "it is reasonable to conclude that Congress expected" the agreements, "like ordinary contracts, to be enforceable." 457 U.S. at 20-21. Petitioners do not dispute that it would be reasonable to conclude that Congress expected the parties to the PPA to have contract remedies to enforce the agreement. Pet. Br. 45. That conclusion does not mean, however, that Congress intended to confer enforceable rights on 340B entities that are not parties to the PPA and on which Congress conferred no private remedy under the Act. *See supra* pp. 3-7.

The government posits that the PPA is not a contract. U.S. Br. 14-21. *But cf. Mobil Oil Exploration & Producing Se., Inc. v. United States*, 530 U.S. 604, 607 (2000); Pet. App. 180a (PPA ¶ VII(g)) (providing that the PPA "shall be construed in accordance with Federal common law"). If the government is correct,

the absence of a contract dooms respondent's third-party beneficiary claim *ab initio*. But even if the PPA is enforceable as a contract, Congress required manufacturers to enter into an agreement with the Secretary, and only the Secretary. And Congress authorized the Secretary, and only the Secretary, to enforce a manufacturer's ceiling price obligations.

### C. Federal Common Law Claims Would Seriously Disrupt The 340B And Medicaid Drug Rebate Programs

1. Even were respondent correct that federal common law presumptively authorizes a cause of action for purported third-party beneficiaries unless Congress displaces that authority, Resp. Br. 2-3, 17, 20, 22, 30, 34-36, Congress plainly did so here. The 340B program and the vastly larger Medicaid program are interrelated, and together those Acts confer powerful enforcement tools on the Secretary, including audit rights, severe civil monetary penalties, and termination of the PPA and federal financial participation for the manufacturer's outpatient drugs covered under State Medicaid plans. Pet. Br. 38-39; U.S. Br. 4, 30-31.

The 340B and Medicaid Acts, taken together, establish a comprehensive and interwoven statutory scheme that vests exclusive and centralized enforcement authority with the Secretary, who has the expertise to uniformly enforce both programs. Pet. Br. 37-39, 41; U.S. Br. 29-33; Br. of PhRMA as Amicus Curiae 20-22. As the government agrees, the availability of private suits by over 14,500 covered entities to challenge any and all AMP and BP pricing decisions would seriously disrupt the administration of both the 340B and Medicaid Rebate Acts. Pet. Br. 32-42; U.S. Br. 33-34. Because Congress has

"occupied the field through the establishment of a comprehensive regulatory program supervised by an expert administrative agency," federal common law remedies are foreclosed. *City of Milwaukee v. Illinois*, 451 U.S. 304, 317 (1981); *see also Northwest Airlines, Inc. v. Transp. Workers Union of Am.*, 451 U.S. 77, 95-99 (1981).

Common law suits would permit 340B entities to challenge the judgments used by manufacturers in calculating AMP or BP for tens of thousands of pharmaceutical products for which Medicaid rebates are paid. Br. of PhRMA as Amicus Curiae 22-23. Although respondent has not identified a drug product for which it believes it was overcharged, Pet. App. 29a, 112a, this suit purports to challenge each and every AMP and BP reported by nine large manufacturers over an eight-year putative class period. *See supra* p. 5. The burdens on manufacturers from suits by 340B entities would be staggering. For example, to produce all AMP and BP information for a sample of only three drugs per manufacturer in the first stage of discovery, the district court observed that,"[i]t is safe to say many millions were spent by defendants producing the responsive materials." Third Am. Case Management Order 1 (N.D. Cal. July 9, 2010).

It also is difficult to overstate the breadth and complexity of the pricing methodology under the 340B and Medicaid Rebate programs. *E.g.*, Pet. Br. 34-37. AMP, for example, was defined as the average price paid by wholesalers in the United States for drugs dispensed to the "retail pharmacy class of trade." 42 U.S.C. § 1396r-8(k)(1). The Medicaid Act did not define the terms "wholesalers" or "retail pharmacy class of trade." Nor did the Centers for

Medicare & Medicaid Services ("CMS") interpret those terms in regulations from the inception of the Medicaid Rebate program in 1990 through 2007.

Because AMP is an "average" of prices charged in commercial transactions, manufacturers must (1) calculate the number of drug units sold, drug unit prices, and commercial rebates or other price concessions provided for all sales of a covered drug in each reporting period; (2) determine which of those sales must be included in AMP (because they are to a customer in the "retail pharmacy class of trade") and which of those sales must be excluded from AMP (because they are to customers outside the "retail pharmacy class of trade"); and then (3) calculate the weighted average of the includable sales prices, net of any price concessions. *See, e.g.*, 72 Fed. Reg. 39,142, 39,146-49 (July 17, 2007). These calculations are even more complex because some sales are made to wholesalers, who in turn sell product to the end user. Some of those end users are retail customers while others are not. The calculation of BP also is quite complex. For example, because the "Best Price" is not simply the manufacturer's lowest price on *any* sale, but rather is the lowest *net* price to a *non-excluded* customer, difficult questions arise concerning which prices are excluded and which are not, as well as what rebates, discounts and other price concessions should be counted to determine the net price. *See, e.g.*, *id.* at 39,149-51.

As PhRMA explains in its amicus brief (at 23), manufacturers devote substantial internal and external resources to the price reporting process and invest substantial sums in sophisticated computer systems to track their sales and rebates and to calculate Medicaid rebates and 340B ceiling prices.

*See also* Pet. Br. 34. The lack of formal agency guidance from 1990 through 2007 made the AMP and BP calculation process all the more difficult. *Id.* at 34-36; Br. of PhRMA as Amicus Curiae 24-25.

Even after the Secretary issued her final rule in 2007, which comprises 104 pages of intricate, detailed, and complex guidance setting forth the categories of sales and price concessions that manufacturers must include and exclude from AMP and BP, the Secretary nevertheless vested manufacturers with discretion to make reasonable assumptions in their AMP and BP calculations in the absence of applicable agency guidance. 72 Fed. Reg. at 39,171; J.A. 78-79 (Medicaid Rebate Agreement § II(i)); Br. of the United States as Amicus Curiae at 5, *County of Santa Clara v. Astra USA, Inc.*, No. 09-15216 (9th Cir. Oct. 27, 2009) ("C.A. Gov't. Br."). Now that the Secretary's AMP regulations have been withdrawn, 75 Fed. Reg. 69,591 (Nov. 15, 2010), manufacturers confront additional questions of statutory interpretation in calculating AMP. Courts or perhaps juries in common law breach of contract actions should not be permitted to impose liability on manufacturers for making reasonable interpretations with respect to the AMP and BP treatment of potentially millions of drug transactions under highly technical and complex statutes that centralize enforcement of both programs with the Secretary.

Respondent further does not dispute that the interests of 340B entities and the Medicaid program conflict with respect to AMP. Pet. Br. 40-41. A lower AMP generally reduces the ceiling price paid by 340B entities but at the same time reduces the amount of Medicaid rebates paid to the States under the Medicaid program. *Id.*; C.A. Gov't Br. 31. As the Secre-

tary explained to the court of appeals, "if both 340B entities and states can bring separate suits over AMP calculations, there is a real possibility that manufacturers could be subject to inconsistent obligations." C.A. Gov't Br. 31-32; *see also* U.S. Br. 34.

Respondent is wrong that the conflict concerning AMP is merely "hypothetical." Resp. Br. 58. Respondent itself has alleged that petitioners miscalculated their AMPs and has sought extraordinarily extensive, burdensome, and costly discovery from manufacturers with respect to their AMP calculations. *See, e.g.*, Pet. App. 74a (respondents seek "[a]ll information . . . underlying [petitioners'] determination of AMP and BP"). States have alleged that manufacturers should have reported a *higher* AMP. *See Massachusetts v. Mylan Labs.*, 357 F. Supp. 2d 314, 321 (D. Mass. 2005). And the U.S. Department of Justice has pursued False Claims Act litigation against at least one pharmaceutical company (King Pharmaceuticals) for, among other things, allegedly misreporting its AMPs. *See* Press Release, Dep't of Justice (Nov. 1, 2005), *available at* www.justice.gov/opa/pr/2005/November/05_civ_581.html. Again, Congress, the Secretary, and manufacturers alike contemplated that the Secretary exclusively would enforce a manufacturer's pricing obligations under the 340B Act, not that manufacturers would be hauled into court by up to 14,500 different entities that have neither the expertise nor obligation to consider potentially conflicting objectives of the much larger Medicaid Rebate program.

2. Respondent downplays the above concerns by suggesting that "[t]o the extent difficult issues arise, they can be dealt with through primary jurisdiction referrals." Resp. Br. 51. But "referral to HHS would

depend on a case-by-case judicial determination, and could interfere with HHS's enforcement priorities." U.S. Br. 35 n.15 (internal citation omitted). More fundamentally, the Secretary has *exclusive* jurisdiction to enforce a manufacturer's ceiling price obligations by administering the 340B Act on a centralized, uniform basis. A common law regime of piecemeal referrals to the Secretary is not the scheme passed by Congress.

Respondent, citing by analogy the False Claims Act ("FCA"), 31 U.S.C. § 3729 *et seq.*, argues that private enforcement suits are "well-suited" to enhance the Secretary's enforcement efforts. Resp. Br. 50. The FCA, however, contains protections that do not apply to ordinary breach of contract suits. Significantly, FCA suits are subject to the control of the United States, 31 U.S.C. § 3730(c)(2)(A), and seek damages on behalf of the United States. Thus, FCA suits safeguard the interests of the United States, not interests of 340B entities that could well diverge from those of the United States. The FCA also requires the relator to allege that a defendant has "knowingly" made a "false or fraudulent claim," *id*. § 3729(a)(1), and to satisfy the heightened pleading requirements for fraud. *See* John T. Boese, *Civil False Claims and Qui Tam Actions* § 5.04 (4th ed. & Supp. 2011-1). A common law breach of contract suit contains none of those protections.

Respondent also points to the Secretary's position that the Medicaid Act does not preempt States from pursuing state law fraud claims against manufacturers. Resp. Br. 49-50, 54-55. But the issue of whether a federal statute preempts state law is distinct from the question presented here, which is whether Congress conferred on 340B entities a federal

common law right to enforce the 340B Act. *See City of Milwaukee*, 451 U.S. at 316.

Respondent also laments that Congress passed the 340B Act without giving 340B entities a right to enforce the Act in court. Resp. Br. 34. That deliberate choice by Congress is all the more reason to preclude courts from creating such remedies under common law. Congress vested the Secretary with comprehensive authority to enforce a manufacturer's drug pricing obligations. That is enough to displace a common law remedy. *City of Milwaukee*, 451 U.S. at 324. Courts may "disagree with the regulatory approach taken by the agency with responsibility," but "such disagreement alone is no basis for the creation of federal common law." *Id.* at 323.

Respondent discusses a series of FCA settlements by drug manufacturers alleging violations of the BP requirements of the Medicaid Act. Resp. Br. 9-11, 50-55. As an initial matter, those settlements go a long way in refuting respondent's insistence that federal administrative oversight and enforcement efforts have been "virtually non-existent." Resp. Br. 11; *accord id.* at 55-58. AMP and BP calculations by the pharmaceutical industry are subject not only to extensive internal controls and independent audits, but also to on-going government oversight under the Medicaid Act, qui tam actions under the FCA, a federally-funded Health Care Fraud and Abuse Control Program, 42 U.S.C. § 1320a-7c, and other statutory and regulatory requirements.

It also is important to put the FCA settlements into their proper context. The FCA imposes substantial penalties of $5,500-$11,000 per violation, treble damages, and attorney's fees. 31 U.S.C. §§ 3729(a)(1), 3730(d). Further, Section 1128B of the Social

Security Act grants the Department of Health and Human Services Office of Inspector General ("OIG") discretion to exclude drug manufacturers from federal healthcare programs where the Secretary has determined that a false or improper claim was made. *See* 42 U.S.C.§ 1320a-7(b)(7); 42 C.F.R.§ 1001.901.

Accordingly, the government has an extraordinary array of tools at its disposal to extract concessions from pharmaceutical companies even where those companies have good faith arguments against liability. Notwithstanding the comprehensive efforts by manufacturers to comply with applicable guidelines, "the evolving use by the government of the fraud and abuse laws" often has "force[d] settlements by drug and device manufacturers for conduct that was, in large part, viewed by FDA and other agencies as acceptable industry practice until DOJ and OIG began to redefine the regulatory landscape." Marc J. Scheineson & Shannon Thyme Klinger, *Lessons from Expanded Government Enforcement Efforts Against Drug Companies*, 60 Food & Drug L.J. 1, 7 (2005).

The FCA allegations cited by respondent often were premised upon manufacturers' reasonable interpretation of the complex, ambiguous, and often inconsistent regulatory regime described above. As but one example, the private-label settlements entered into by Aventis, Bayer, GlaxoSmithKline, and Bristol-Myers Squibb, *see* Resp. Br. 9, involved the judgments by those companies to exclude from their BP determinations the price charged in the sale of certain products to Kaiser, a health maintenance organization with its own drug packaging facility that relabeled the products under Kaiser's own National Drug Code ("NDC"). In 1997, CMS issued a guidance document, Rebate Release No. 29, which

instructed manufacturers to exclude from BP "sales to other manufacturers who repackage/re-label under the purchaser's NDC." CMS, Medicaid Drug Rebate Program Release No. 29 (1997), *available at* http://www.cms.gov/MedicaidDrugRebateProgram/03_DrugMfrReleases.asp.

Because Kaiser sold the Aventis, Bayer, GlaxoSmithKline, and Bristol-Myers Squibb products under Kaiser's NDC, these manufacturers construed Rebate Release No. 29 to exclude their Kaiser sales from BP. CMS subsequently determined in Rebate Release Nos. 47 and 68, however, that manufacturers should include sales to re-labelers that are also HMOs in their BP calculations. CMS, Medicaid Drug Rebate Program Release No. 47 (2000) & No. 68 (2005), *available at* http://www.cms.gov/MedicaidDrugRebateProgram/03_DrugMfrReleases.asp. Far from supporting improper conduct, these settlements reflect a good faith disagreement over proper interpretation of ambiguous and conflicting guidance issued by CMS. Neither 340B entities nor juries are better positioned to make those difficult and complex judgments.

FCA settlements also often contain a recovery for 340B entities. *See* Kirsten V. Mayer, *The Medicaid/340B Program "Best Price" Enforcement Landscape*, Big Four Pharmaceutical Pricing Boot Camp 3-5 (2007). To the extent respondent complains that 340B entities received "[o]nly a small portion of those settlement dollars," Resp. Br. 9, 340B entities' expenditures are only a small fraction of Medicaid's expenditures. *Compare Medicaid Prescription Drug Reimbursement: Hearing Before the H. Energy and Commerce Subcomm. on Oversight and Investigations*, 108th Cong. 1 (2004) (testimony of Dennis Smith,

Dir. of CMS) ("In 2003, Medicaid spent more than $34 billion on prescription drugs."), *with* OIG, *Review of 340B Prices* 1 (2006) ("The 340B entities spent an estimated $3.4 billion on covered outpatient drugs in calendar year 2003.").

### D. Covered Entities Are Not Intended Third-Party Beneficiaries Under The Common Law

As discussed, by disavowing that this case turns on the Secretary's intent in entering into the PPA, respondent no longer defends the Ninth Circuit's holding that the contracting parties intended to confer enforceable rights on 340B entities. Respondent nonetheless contends that petitioners waived the issue. Resp. Br. 22, 33, 47. Respondent is wrong.

To be sure, petitioners' primary submission is that a third-party beneficiary common law action would impermissibly circumvent this Court's private right of action jurisprudence. Petitioners also have strenuously argued, however, that the contracting parties never intended the PPA to create rights in favor of non-parties. *E.g.*, Pet. Br. 30 ("[P]ermitting this challenge would 'accord . . . rights never intended by the PPA's signatories.'") (quoting C.A. Gov't Br. 13); *accord* Pet. 33 (same); Pet. Reply 5 (arguing that the decision below strayed "far from the mainstream" in holding that the contracting parties intended to create enforceable rights).

Moreover, as respondent observes, the common law would not permit this suit if it conflicted with the objectives of the 340B Act. Resp. Br. 32 (citing Restatement (Second) of Contracts § 313(1)). Petitioners consistently have argued that common law suits would conflict with Congress's judgment to vest

exclusive enforcement authority with the Secretary and would disrupt the administration of both the 340B and Medicaid Rebate Acts. Pet. Br. 32-42; Pet. 21-24; Pet. Reply 6-9. Thus, even assuming a common law action may proceed in the absence of an implied right of action, the decision below should be reversed.

* * * * *

Suits under the common law create the same separation of powers issues and disruption to the statutory scheme as suits under the statute. No matter the form in which respondent seeks to enforce the 340B Act's ceiling price provisions, Congress declined to authorize private enforcement of those provisions. That principle controls this case.

## CONCLUSION

For the foregoing reasons and the reasons stated in petitioners' opening brief, the decision below should be reversed.

Respectfully submitted,

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