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 U.S. Court of Appeals for the Ninth Circuit**

## BRIEF FOR APA WATCH AS *AMICUS CURIAE* SUPPORTING PETITIONERS

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## QUESTION PRESENTED

Section 340B of the Public Health Service Act, 42 U.S.C. §256b, imposes ceilings on the prices that drug manufacturers may charge for prescription medicines sold to specified health care facilities and entities, known as "340B entities." Section 340B implements the ceiling prices by requiring the Secretary of Health and Human Services to enter into contracts setting forth the Act's pricing restrictions, and drug manufacturers are required to enter into those contracts as a condition of participation in Medicaid. 42 U.S.C. §§1396b(i)(10), 1396r-8(a)(1), (a)(5).

In the decision below, the Ninth Circuit held that covered 340B entities have a private right of action under "federal common law" to enforce the Act's pricing requirements, even though the Act itself contains no express or implied private right of action. The Ninth Circuit held that a plaintiff may pursue a federal common-law claim as a third-party beneficiary of a contract that embodies statutory requirements.

The question presented is whether, in the absence of a private right of action to enforce a statute, federal courts have the federal common-law authority to confer a private right of action on non-parties to the contract simply because the statutory requirement sought to be enforced is embodied in the contract.

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## INTEREST OF *AMICUS CURIAE*[1]

*Amicus curiae* APA Watch is a nonprofit membership corporation headquartered in McLean, Virginia. APA Watch has participated as *amicus curiae* before this Court and the Courts of Appeals on third-party enforcement and justiciability issues.

[1] This *amicus* brief is filed with written consent of all parties; the written letters of consent from petitioners and respondent have been lodged with the Clerk of the Court. Pursuant to Rule 37.6, counsel for *amicus curiae* authored this brief and no counsel for a party authored this brief in whole or in part, nor did any person or entity other than the *amicus* and its counsel make a monetary contribution to the preparation or submission of this brief.

*See, e.g., Stormans Inc. v. Seleky,* No. 07-36039 (9th Cir.) (third-party justiciability); *Envtl. Defense v. Duke Energy Corp.,* No. 05-848 (U.S.) (third-party enforcement). Although the third-party enforcement here does not directly affect APA Watch members, second-guessing agency enforcement and disrupting the contract parties' expectations present an issue of fairness on which APA Watch seeks to comment. Moreover, because the litigants have not briefed the plaintiff's standing, APA Watch's perspective on third-party justiciability could aid the Court on a jurisdictional issue antecedent to the parties' merits arguments. For these reasons, APA Watch respectfully files this *amicus* brief.

## FACTUAL AND LEGAL BACKGROUND

In this action, respondent Santa Clara County, California ("Santa Clara") seeks damages from petitioners Astra USA, Inc., AstraZeneca Pharmaceuticals LP, Aventis Pharmaceuticals Inc., Bayer Corp., Bristol-Myers Squibb Co., Pfizer Inc., Merck & Co., Inc. (f/d/b/a Schering-Plough Corp.), SmithKline Beecham Corp. (d/b/a GlaxoSmithKline), TAP Pharmaceutical Products Inc. (n/k/a Takeda Pharmaceuticals North America, Inc.), Wyeth, Inc., Wyeth Pharmaceuticals, Inc., Zeneca Inc., and ZLB Behring LLC (collectively, the "Manufacturers") under standard Pharmaceutical Pricing Agreement ("PPA") contracts that the Manufacturers enter with the federal Department of Health & Human Services ("HHS"). This section sets forth the factual and legal background relevant to the proceeding in this Court.

### Procedural Background

Santa Clara sued the Manufacturers on a variety of federal- and state-law theories, initially in state court but subsequently removed to the U.S.

District Court for the North District of California. The District Court dismissed under FED. R. CIV. P. 12(b)(6) for failure to state a claim on which relief could be granted. Applying the federal common law of contracts, the U.S. Court of Appeals for the Ninth Circuit reversed with respect to Santa Clara's claim to enforce the PPA's provisions for discounted drug prices as an intended direct beneficiary of the PPAs. Although the complaint sought relief under several legal theories, this appeal concerns only the right to sue under the PPA as a third-party beneficiary.

**Statement of Facts**

Although not material to this *amicus* brief, the facts are the allegations set forth in Santa Clara's complaint. J.A. 28-66. Although not a fact *per se,* the complaint also makes clear the legal theory that Santa Clara "and all similarly situated counties … are the intended beneficiaries" of the PPA. Compl. ¶44, J.A. at 45. The only relevant fact are (1) the PPA's express terms, and (2) that HHS has not invoked PPA ¶IV(c)'s dispute-resolution provisions with respect to the discounts that the Manufacturers allegedly have withheld.

**Medicaid Drug Rebate Program**

Medicaid "impose[s] a general requirement that, in order to qualify for Medicaid payments, drug companies must enter into agreements … with [HHS] … to provide rebates on their Medicaid sales of outpatient prescription drugs." *Pharm. Research & Mfrs. of Am. v. Walsh,* 538 U.S. 644, 652 (2003). Having rebate agreements in effect pursuant to §1396r-8 is a condition of Manufacturers' participating in Medicaid. 42 U.S.C. §1396b(i)(10), (a)(1), (a)(5). Medicaid provides various means for HHS to enforce the requirement that Manufacturers

provide the required rebates, 42 U.S.C. §§1396r-8(b)(3)(B), 1396r-8(b)(3)(C)(i)-(ii), 1396r-8(b)(4)(B)(i), but does not include a private cause of action.

**§340B Drug Ceiling Price Program**

Section 340B of the Public Health Service Act of 1992, 42 U.S.C. §256b (hereinafter, "§340B"), requires Manufacturers participating in Medicaid to offer discounted drug prices to qualifying clinics and other healthcare facilities – known as "340B entities" or "safety net providers" – that receive federal funds. 42 U.S.C. §256b(a)(4). The §340B program links to the Medicaid rebate program, 42 U.S.C. §§256b(a)(1), 1396r-8(a)(1), (a)(5), which HHS implements through its standard PPA contract. Pet. App. 165a. Like the larger Medicaid rebate program, the §340B program does not include a private cause of action.

**Pharmaceutical Pricing Agreements**

As relevant to this litigation, the standard HHS PPA contract is set forth in the Appendix to the Manufacturers' Petition for *Certiorari* at Pet. App. 165a-181a. This standard PPA provides five provisions relevant to this litigation:

1. Paragraph IV(c) provides a dispute-resolution provision that is the only contractual vehicle under which the Manufacturers must reimburse discounts to covered entities:

> If [HHS] believes that the Manufacturer has not complied with the provisions of the Agreement, or has refused to submit reports, or has submitted false information pursuant to the Agreement, the Secretary, at his discretion, may initiate the informal dispute resolution process. If so found, the Secretary may require the Manufacturer to reimburse

> the entity for discounts withheld and can also terminate the Agreement.

PPA ¶IV(c), Pet. App. 174a. Significantly, this refund provision expressly provides discretion to HHS and does not discuss or contemplate enforcement directly by covered entities such as Santa Clara.

2. Paragraph IV(e) provides that "[n]othing in [Paragraph IV] shall preclude the Manufacturer or [HHS] from exercising such other remedies as may be available by law." PPA ¶IV(e), Pet. App. 175a.

3. Paragraph VI(c) provides that "[t]he Secretary may terminate the Agreement for a violation of the Agreement or other good cause upon 60 days prior written notice to the Manufacturer of the existence of such violation or other good cause" and that "[d]isputes arising under a contract between a Manufacturer and a covered entity should be resolved according to the terms of that contract." PPA ¶VI(c), Pet. App. 177a. Paragraph VI(c) further requires HHS to provide terminated Manufacturers the opportunity to participate in the dispute-resolution process concerning their termination. *Id.*

4. Paragraph VII(f) provides that "[n]othing in the [PPA] shall be construed as a waiver or relinquishment of any legal rights of the Manufacturer or [HHS] under the Constitution, the Act, or Federal laws, or State laws." PPA ¶VII(f), Pet. App. 180a.

5. Paragraph VII(g) provides that the PPA "shall be construed in accordance with Federal common law" and that "ambiguities shall be interpreted in the manner which best effectuates the statutory scheme." PPA ¶VII(g), Pet. App. 180a.

As set forth in more detail in the Argument, these contractual provisions, taken together, provide the exclusive mechanism *under this contract* for requiring the Manufacturers to reimburse covered entities such as Santa Clara, PPA ¶IV(c),[2] require resolution of any disputes between Manufacturers and entities like Santa Clara be resolved under the contract between the entity and the Manufacturer, PPA ¶VI(c), and require that any ambiguities be resolved in the manner that best effectuates the statutory scheme. PPA ¶VII(g). As indicated, that statutory scheme does not contemplate private enforcement by covered entities such as Santa Clara.

**Federal Common Law**

"This Court has consistently held that federal law governs questions involving the rights of the United States arising under nationwide federal programs." *U.S. v. Kimbell Foods, Inc.,* 440 U.S. 715, 726 (1979). Thus, "[f]ederal law typically controls when the Federal Government is a party to a suit involving its rights or obligations under a contract." *Boyle v. United Tech. Corp.,* 487 U.S. 500, 519 (1988); *cf. Empire Healthchoice Assur., Inc. v. McVeigh,* 547 U.S. 677, 691 (2006) ("Court has made clear that uniform federal law need not be applied to all questions in federal government litigation, even in cases involving government contracts") (internal quotations omitted). For *private enforcement* of a

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[2] Although the PPA's dispute-resolution provision does not prevent HHS from enforcing the Manufacturers' statutory obligations via other means, PPA ¶IV(e), Pet. App. 175a, the other means are irrelevant to this litigation, which concerns only enforcement via the PPA itself.

federal contract or program, however, a uniform federal rule of decision is not required if the claim "will have *no direct effect upon the United States or its Treasury*." *Boyle,* 487 U.S. at 520 (*quoting Miree v. DeKalb County,* 433 U.S. 25, 29 (1977)) (emphasis in *Boyle*). While this Court typically applies federal common law to litigation involving the federal government, it does not necessarily do so for private enforcement of the same federal provisions.

Here, the contracting parties themselves – including a federal agency – have adopted a contract that expressly invokes the federal common law. While that could resolve the issue, it need not: "[c]ontroversies directly affecting the operations of federal programs, although governed by federal law, do not inevitably require resort to uniform federal rules." *Kimbell Foods,* 440 U.S. at 727-28. This Court could adopt a federal rule of decision that looks to state law: "when there is little need for a nationally uniform body of law, state law may be incorporated as the federal rule of decision." *Kimbell Foods,* 440 U.S. at 728. Indeed, "[t]he prudent course … is often to adopt the readymade body of state law as the federal rule of decision until Congress strikes a different accommodation." *McVeigh,* 547 U.S. at 691-92 (internal quotation omitted). Notwithstanding that the contracting parties elected the federal common law, the federal rule of decision nonetheless could be "*See the state rule.*"

Finally, "federal programs that by their nature are and must be uniform in character throughout the Nation necessitate formulation of controlling federal rules." *Kimbell Foods,* 440 U.S. at 728 (*citing United States v. Yazell,* 382 U.S. 341, 354 (1966)) (interior quotations omitted). "[A]bsent some congressional

authorization to formulate substantive rules of decision, federal common law exists only in such narrow areas as those concerned with the rights and obligations of the United States, interstate and international disputes implicating conflicting rights of States or our relations with foreign nations, and admiralty cases." *Texas Industries, Inc. v. Radcliff Materials, Inc.,* 451 U.S. 630, 641 (1981) (footnotes omitted). Generally, therefore, this Court has discretion "[w]hether to adopt state law or to fashion a nationwide federal rule," *Kimbell Foods,* 440 U.S. at 728, based on "a variety of considerations … relevant to the nature of the specific governmental interests and to the effects upon them of applying state law." *U.S. v. Standard Oil Co.,* 332 U.S. 301, 310 (1947). In sum, this Court makes a case-by-case determination on the need for uniform federal rules, based on the totality of the circumstances.

In light of the highly technical nature of both the PPA and the underlying statutes and of the national scope of this litigation through Santa Clara's purporting to represent all similarly situated entities, *amicus* APA Watch respectfully submits that this Court should adopt uniform federal rules of decision. As it happens, however, the rules would be the same under California or federal law.

## SUMMARY OF ARGUMENT

As signaled by the preceding subsection, this case calls upon this Court to adopt a rule of decision under the federal common law. While the parties focus on the availability of a third-party cause of action under the federal common law, *amicus* APA Watch respectfully submits that this Court first must adopt a federal rule of decision for third-party beneficiaries' standing to enforce contracts.

The standing inquiry assumes *arguendo* the plaintiff's merits views (here, that the federal common law provides a cause of action for third-party beneficiaries to enforce the PPA) and then asks whether the plaintiff meets the constitutional and prudential tests for standing. Because it is integral to federal jurisdiction, the standing inquiry comes first. If Santa Clara lacks standing, the case must be dismissed for lack of jurisdiction under FED. R. CIV. P. 12(b)(1), without reaching the lack of a cause of action under FED. R. CIV. P. 12(b)(6).

Notwithstanding that this Court must assume Santa Clara's non-frivolous merits views to evaluate jurisdiction, Section I, *infra,* argues that Santa Clara lacks standing to enforce the PPA as a third-party beneficiary because *even the United States* could not enforce the PPA under contract law, without first invoking the PPA's dispute-resolution provisions. What the promisee lacks a vested right to enforce directly, a third-party beneficiary lacks a cognizable right to enforce indirectly, regardless of whether that third party could enforce the contract after the right vests for the promisee.

If – contrary to the argument in Section I, *infra* – Santa Clara survives the standing analysis, this Court nonetheless should hold that Santa Clara lacks a cause of action to enforce the PPA for the two reasons set out in Section II, *infra.* First, as the Manufacturers argue, the relevant statutes do not create a cause of action, and HHS lacks authority to create a cause of action. *See* Manufacturers' Br. at 18-21. This first reason would constitute a bright-line rule of federal common law. Second, the PPA expressly provides that it "shall be interpreted in the manner [that] best effectuates the statutory scheme,"

PPA ¶VII(g), Pet. App. 180a, and expressly directs enforcement between the Manufacturers and covered entities such as Santa Clara to proceed under the contract between those parties, PPA ¶VI(c), Pet. App. 177a, thereby disavowing an intent that such third parties enforce the PPA under the PPA. Even if this Court avoids a bright-line rule against common-law enforcement by third-party beneficiaries lacking a statutory cause of action, this Court should interpret *this contract* to prohibit that intrusion into the statutory scheme.

## ARGUMENT

Although this Court's "normal role is to interpret law created by others and not to prescribe what [the law] shall be," *Danforth v. Minnesota,* 552 U.S. 264, 290 (2008) (internal quotation omitted), "this Court has ultimate authority to determine and declare" the federal common law. *Taylor v. Sturgell,* 553 U.S. 880, 891 (2008). Here, federal law obviously applies – under Article III for jurisdiction and under the PPA's express terms for the merits – but "[t]he more difficult task … is giving content to this federal rule." *Kimbell Foods,* 440 U.S. at 727. However this Court gives content to the federal rules of decision for standing and for causes of action, *amicus* APA Watch respectfully submits that this litigation must be dismissed. Santa Clara has no cognizable right, much less a right of action, under the PPAs.

### I. SANTA CLARA LACKS STANDING TO BRING ITS COMMON-LAW CLAIM

Article III limits federal courts to "cases" and "controversies," U.S. CONST. art. III, §2, which requires an actual or imminent "injury in fact" to a cognizable interest. *Lujan v. Defenders of Wildlife,*

504 U.S. 555, 560 (1992). Specifically, constitutional standing presents a tripartite test: "an invasion of a *legally protected interest*" of the plaintiff, caused by the defendants, and redressable by a court. *Defenders of Wildlife,* 504 U.S. at 560-62 (emphasis added). Although Santa Clara's injury arguably results from the United States' discretionary non-enforcement, *amicus* APA Watch assumes *arguendo* that Santa Clara could make out a case for causation and redressability. Santa Clara's problem is more basic. Third-party beneficiaries lack cognizable rights to enforce contractual provisions that the promisee itself could not enforce under the contract.[3]

### A. The Manufacturers Cannot Waive Santa Clara's Lack of Standing

Although the Manufacturers have not contested standing, litigants cannot confer federal jurisdiction by consent or waiver: "no action of the parties can confer subject-matter jurisdiction upon a federal court." *Insurance Corp. of Ireland v. Compagnie des Bauxites de Guinee,* 456 U.S. 694, 702 (1982); *FW/PBS, Inc. v. City of Dallas,* 493 U.S. 215, 231 (1990); *Steel Co. v. Citizens for a Better Env't,* 523 U.S. 83, 95 (1998). To the contrary, because it goes to the Article III "power of the court to entertain the suit," standing "is *the threshold question* in every federal case." *Warth v. Seldin,* 422 U.S. 490, 499 (1975) (emphasis added). "'Without jurisdiction the court cannot proceed at all in any

[3] Although the PPA does not preclude HHS from enforcing the statutes via other means, *see* note 2, *supra,* this litigation concerns only enforcement of the PPA *as a contract.*

cause. Jurisdiction is power to declare the law, and when it ceases to exist, the only function remaining to the court is that of announcing the fact and dismissing the cause.'" *Steel Co.,* 523 U.S. at 94 (*quoting Ex parte McCardle,* 74 U.S. (7 Wall.) 506, 514 (1868)). Consequently, Santa Clara's standing is antecedent to the cause-of-action question on which the parties join. *Steel Co.,* 523 U.S. at 89-90:

> *It is firmly established in our cases that the absence of a valid … cause of action does not implicate subject-matter jurisdiction,* i.e., *the courts' statutory or constitutional* power *to adjudicate the case.*

*Id.* at 89 (emphasis in original); *Northwest Airlines, Inc. v. County of Kent,* 510 U.S. 355, 365 (1994) ("[t]he question whether a federal statute creates a claim for relief is not jurisdictional"). Under its precedents – and its constitutional jurisdiction – this Court must evaluate standing before the cause-of-action issue addressed in Section II, *infra.* If Santa Clara lacks standing, that ends the inquiry.

### B. Santa Clara Must Establish its Own Standing to Pursue this Litigation

It is, of course, "axiomatic" that a "litigant first must clearly demonstrate that [it] has suffered an injury in fact in order to assert Article III standing to sue." *Wyoming v. Oklahoma,* 502 U.S. 437, 465 (1992) (interior quotations omitted). Because plaintiffs bear the burden of establishing their standing, federal courts "presume that [they] lack jurisdiction unless the contrary appears affirmatively from the record." *Renne v. Geary,* 501 U.S. 312, 316 (1991). As explained in the next section, Santa Clara lacks standing under the PPA.

Significantly, Santa Clara lacks standing to litigate the United States' injuries. A plaintiff can assert the rights of absent third parties only if the plaintiff itself has constitutional standing, the plaintiff and the absent third parties have a "close" relationship, and a sufficient "hindrance" keeps the absent third party from protecting its own interests. *Kowalski v. Tesmer,* 543 U.S. 125, 128-30 (2004) (*citing Powers v. Ohio,* 499 U.S. 400, 411 (1991)). Here, Santa Clara fails all three prongs: (1) it lacks standing in its own right, (2) it lacks the requisite close relationship with the federal government, and (3) nothing hinders HHS from proceeding against the Manufacturer if Santa Clara is correct on the merits.

Analogously, Santa Clara cannot rely on other counties or similarly situated entities to establish Santa Clara's standing, notwithstanding that Santa Clara sues in a representative capacity: "if none of the named plaintiffs purporting to represent a class establishes the requisite of a case or controversy with the defendants, none may seek relief on behalf of [itself] or any other member of the class." *O'Shea v. Littleton,* 414 U.S. 488, 494 (1974). For Santa Clara to pursue this litigation, therefore, Santa Clara must establish its own standing.

### C. Third-Party Beneficiaries Lack Standing to Enforce Contracts that Have Not Vested in the Promisee

At the outset, only *intended* beneficiaries have standing to enforce an agreement. *Karo v. San Diego Symphony Orchestra Ass'n,* 762 F.2d 819, 821-22 (9th Cir. 1985); *Garcia v. Truck Insurance Exchange,* 36 Cal.3d 426, 436-37 (1984). Those who are not intended beneficiaries are mere interlopers who lack standing to sue to enforce other parties' contract.

*More v. Churchill,* 155 Cal. 368, 369-70 (1909). But even intended third-party beneficiaries "generally have no greater rights in a contract than does the promise[e]." *United Steelworkers of Am. v. Rawson,* 495 U.S. 362, 375 (1990), which links the third-party beneficiaries' rights to the same conditions as the promisee's rights. RESTATEMENT (SECOND) OF CONTRACTS §304 comment b. To the extent that Santa Clara depends on the Manufacturers' PPA obligations to HHS, the rights of Santa Clara are subject to the same conditions precedent as the rights of HHS. *What HHS could not do directly as the promisee, Santa Clara cannot do indirectly as a third-party beneficiary.*

Under *Miree v. DeKalb County,* 433 U.S. 25, 28 (1977), federal courts can look to state law for third-party beneficiaries' standing to enforce federal obligations. California follows the RESTATEMENT (SECOND) OF CONTRACTS, *Martinez v. Socoma Companies, Inc.,* 11 Cal.3d 394, 401-02, 404-05 (1974) (citing RESTATEMENT OF CONTRACTS and then-tentative drafts of the RESTATEMENT (SECOND) OF CONTRACTS); *Outdoor Services, Inc. v. Pabagold, Inc.,* 185 Cal.App.3d 676, 683-84 (Cal. App. 1986) (citing RESTATEMENT (SECOND) OF CONTRACTS), as do most other states. *See, e.g., Guy v. Leiderbach,* 501 Pa. 47, 459 A.2d 744, 750-52 (Pa. 1983); *Joseph v. Hospital Service Dist. No. 2,* 939 So.2d 1206, 1213 (La. 2006).

An intended beneficiary must assert a vested right, *Karo,* 762 F.2d at 822 ("he must be seeking to enforce a right that is personal to him and vested in him at the time of the suit"), without which "[h]e does not have standing to sue as a third party beneficiary because he had no vested rights." *Karo,* at 824. A "vested right" is one "not subject to a

condition precedent." *In re Marriage of Bouquet,* 16 Cal.3d 583, 591 n.7 (1976); *Skookum Oil Co. v. Thomas,* 162 Cal. 539, 545 (1912) ("[n]either will equity relieve such [party] who … has not fulfilled conditions precedent to the vesting of his right of action"); *Knudson v. City of Ellensburg,* 832 F.2d 1142, 1147 (9th Cir. 1987). Given that HHS could not have brought this action *under contract law* without completing the PPA dispute-resolution prerequisites, PPA ¶IV(c), Pet. App. 174a, neither HHS nor the Manufacturers intended third-party beneficiaries to enforce the PPA without satisfying the PPA's prerequisites.[4] Under the circumstances, Santa Clara lacks third-party standing to enforce the PPAs.

Unmet conditions precedent can affect both standing under Rule 12(b)(1) and failure to state a claim under Rule 12(b)(6). For example, Louisiana law for stipulations *pour autrui* (*i.e.,* third-party beneficiary contracts) suggests that failure to meet the promisee's conditions precedent renders third-

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[4] *See, e.g., Glock v. Howard & Wilson Colony Co.,* 123 Cal. 1, 16-17 (1898) (when a "contract is made to depend upon a condition precedent" and "[b]y its terms no right is to vest … until certain acts … have been done by [a party]," "a court of equity no more than a court at law will relieve [the party], under such circumstances … in the absence of an equitable showing to excuse his default"); *Chen v. Chen,* 586 Pa. 297, 311-13, 893 A.2d 87, 96 (Pa. 2006) (third-party beneficiary lacked a "legally enforceable interest" and third-party standing based on terms of the agreement between the promisor and promisee); *Avatar Exploration, Inc. v. Chevron, U.S.A., Inc.,* 933 F.2d 314, 318 (5th Cir. 1991) (under Louisiana law, "[a]s third party beneficiaries, their rights under the contract could not exceed [the promisee's] rights").

party beneficiaries unable to state a claim. *Shaw Constructors v. ICF Kaiser Eng'rs, Inc.,* 395 F.3d 533, 540 & n.15 (5th Cir. 2004); *Kane Enter. v. MacGregor (USA) Inc.,* 322 F.3d 371, 375 (5th Cir. 2003). Even if unmet conditions precedent implicated only Rule 12(b)(6) *for promisees,*[5] they nonetheless would implicate jurisdiction for third-party beneficiaries, who lack standing to enforce non-vested rights. *Conoco, Inc. v. Republic Ins. Co.,* 819 F.2d 120, 123-24 (5th Cir. 1987); *Palma v. Verex Assur., Inc.,* 79 F.3d 1453, 1458 (5th Cir. 1996). Without the conditions precedent to PPA enforcement, Santa Clara has no legally protected interest in PPA reimbursement and thus lacks standing here.

Whether this Court adopts a federal rule of decision or relies on California law under *Miree,* third-party beneficiaries plainly lack standing to enforce contractual provisions that even the promisee could not enforce without having met the conditions precedent to contractual enforcement.

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[5] Numerous statutory regimes set conditions precedent to private enforcement to notify the putative defendant of alleged violations and to provide an opportunity to resolve them. *Zipes v. Trans World Airlines, Inc.,* 455 U.S. 385, 398 (1982); *Friends of the Earth, Inc. v. Laidlaw Envtl. Serv. (TOC), Inc.,* 528 U.S. 167, 174-75 (2000); *Hallstrom v. Tillamook County,* 493 U.S. 20, 32-33 (1989). Regardless of "whether the notice provision is jurisdictional or procedural," private enforcement is "barred" and "must be dismissed" if it commenced prior to the required notice. *Hallstrom,* 493 U.S. at 32-33. Even if that is not jurisdictional under constitutional standing, it is fatal under statutory standing, which this Court also can address at this stage. *Ortiz v. Fibreboard Corp.,* 527 U.S. 815, 830-31 (1999).

## II. SANTA CLARA HAS NO COMMON-LAW CAUSE OF ACTION TO ENFORCE THE PPA CONTRACTS

The Manufacturers convincingly demonstrate that HHS lacks authority to create a cause of action by contract that extends beyond the causes of action that Congress provided in the underlying statute. Manufacturers' Br. at 18-42. If it finds that Santa Clara has standing, *but see* Section I, *supra,* this Court should adopt a bright-line rule that the federal common law does not enable a federal agency to expand statutory causes of action beyond the express or implied statutory terms by regulation, contract, or otherwise: "Agencies may play the sorcerer's apprentice but not the sorcerer himself." *Alexander v. Sandoval,* 532 U.S. 275, 291 (2001).[6] The general rule of *Sandoval* applies even more strongly to this contract, where HHS claims not to have intended to create the private right of action in the first place.

Even if the Court declines to adopt a bright-line rule against agencies' expanding private causes of action, the Court nonetheless should find that *this contract* does not expand the private causes of action available to Santa Clara. Paragraph VII(g) of the PPA expressly provides that the PPA "shall be interpreted in the manner [that] best effectuates the statutory scheme." PPA ¶VII(g), Pet. App. 180a. All

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[6] Agency regulations can be enforceable if they implement the statute, as distinct from expanding the statute to prohibit (or allow) conduct that the statute does not prohibit (or allow). *Global Crossing Telecomm., Inc. v. Metrophones Telecomm., Inc.,* 550 U.S. 45, 59 (2007). Here, it is undisputed that the statutes in question do not provide a private cause of action.

of the reasons that the Manufacturers make for private enforcement's being foreign to the underlying statutes apply with even greater force to ¶VII(g)'s less-stringent inquiry into the mere consistency of private enforcement with the statutory scheme. Further, Paragraph VI(c) expressly provides that litigation between the Manufacturers and covered entities such as Santa Clara should proceed under the contract between those parties. PPA ¶VI(c), Pet. App. 177a. Thus, even without a bright-line rule for third-party enforcement of contracts generally, this Court should hold that *this contract* precludes third-party enforcement by entities such as Santa Clara.

## CONCLUSION

For the foregoing reasons, this Court should hold that Santa Clara lacks standing to bring its third-party claim to enforce the United States' PPA contract. If this Court finds that Santa Clara would have standing to enforce the PPA as a third-party beneficiary assuming *arguendo* that the federal common law provides such a cause of action, this Court nonetheless should hold that the federal common law *does not* provide such a cause of action.

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