No. 09-1273

In the
Supreme Court of the United States

ASTRA USA, INC., ET AL.,

Petitioners,

v.

COUNTY OF SANTA CLARA,

Respondent.

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

BRIEF OF PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PhRMA) AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

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INTEREST OF *AMICUS CURIAE*[1]

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is a voluntary, nonprofit association representing the nation's leading research-based pharmaceutical and biotechnology companies. *See* http://www.phrma.org/member_company_list (listing approximately 40 members, international affiliates, and research associates). PhRMA's mission is to advocate in support of public policies that encourage the discovery of life-saving and life-enhancing new medicines for patients by pharmaceutical and biotechnology research companies. PhRMA members invested approximately $45.8 billion in 2009 in the discovery and development of new medicines. *See* 2009 Industry Profile, *available at* http://www.phrma.org/profiles_and_reports.

PhRMA closely monitors legal issues that impact the pharmaceutical and biotechnology industries. To that end, PhRMA has frequently participated in cases before this Court. *See, e.g.*, *Merck & Co., Inc v. Reynolds*, 130 S. Ct. __ (2010) (No. 08-905); *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006) (No. 05-130).

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[1] Counsel of record for all parties were given timely notice of *amicus curiae*'s intention to file this brief as required by Rule 37.2(a) and have consented to its filing. Letters reflecting such consent are on file with the Clerk's Office. No counsel for a party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund its preparation or submission. No person other than *amicus curiae*, its members, or its counsel made a monetary contribution to the preparation or submission of this brief.

This petition is of critical importance to the drug and biologic industries. By holding that 340B entities have a cause of action under federal common law to seek damages as third-party beneficiaries of contracts between the Department of Health and Human Services ("HHS") and drug manufacturers, the decision below exposes PhRMA members to an onslaught of litigation that they — like HHS — could not have imagined. *See* U.S. CA9 Br. 21. The 340B program and the Medicaid drug rebate program from which the 340B program borrows its pricing inputs are vast in scope and rife with technical complexity. If the decision below is left unreviewed, judicially-created damages suits will wreak havoc in this important field, undermining the uniformity and predictability that Congress sought to achieve by delegating the administration of these programs to HHS. PhRMA is filing this brief to underscore why certiorari is needed.

INTRODUCTION AND SUMMARY OF ARGUMENT

In creating the 340B program, Congress sought to conserve federal resources and maximize healthcare coverage by allowing certain favored purchasers to buy drugs at a discount. Congress did not, however, provide a private cause of action to allow 340B entities to enforce the statute's discount pricing provisions through damages suits. That should be the end of the story. The law is now clear that unless Congress intends to create a cause of action, "a cause of action does not exist and courts may not create one." *Alexander v. Sandoval*, 532 U.S. 275, 286-87 (2001).

For the Ninth Circuit, however, Congress's failure to provide a damages remedy was a point of departure. The court below viewed Congress's failure to provide a cause of action as an invitation to augment Congress's work via the federal common law. That maneuver is out of step with the entire thrust of this Court's recent jurisprudence on implied causes of action, the limited scope of federal common law, and the proper role of the Article III courts. Limits on courts' authority to infer rights of action from silent federal statutes are hardly meaningful if courts can simply retreat to federal common law to fashion the same remedy. The decision below exemplifies a view of the role of the federal courts in our system of separated powers that this Court laid to rest long ago.

The Ninth Circuit's circumvention of this Court's implied rights of action precedents is especially problematic because of the nature of the regulatory scheme at issue here. Congress implemented the 340B program using pricing metrics — "Average Manufacturer Price" ("AMP") and "Best Price" ("BP") — that it adopted unchanged from the Medicaid drug rebate program. Injecting uncertainty and potential inconsistency into the determination of those pricing metrics through judicially-created federal common law claims will undermine the orderly and reasonable administration of not only the 340B program, but also the far larger Medicaid rebate program. AMP and BP are not self-evident mechanical computations; to the contrary, the rules of their calculation in the dynamic and complex pharmaceutical marketplace require the application of thoughtful policy judgments. Congress made clear that those judgments were to be made by HHS

subject to APA review, not by the federal courts in a freewheeling exercise in federal common law. And judgments about how to determine AMP and BP necessarily must apply to both programs. A drug cannot have one AMP (or BP) for a 340B purchaser and a different amount or calculation methodology for a state Medicaid agency. Moreover, the Ninth Circuit's focus on the 340B purchasers as the intended beneficiaries ignores the interrelationship between the interests of 340B purchasers and the States: a higher AMP benefits States by raising their Medicaid rebate payments but harms 340B entities by raising the ceiling price for their purchases. HHS can make a single determination subject to review under APA principles that give appropriate deference to HHS. Private damages actions can neither yield a single determination nor provide for appropriate deference. Congress's decision to confer the administration of these programs to HHS should be respected rather than treated as an invitation for judicial creativity.

The Ninth Circuit's decision exposes drug manufacturers to the threat of lawsuits by over 14,500 340B entities, relating to thousands of drug products, challenging AMP and BP as reported to HHS in scores of months and quarters, and involving billions in purchases. All of this would be governed by the vagaries of federal common law. Neither party to the Pharmaceutical Pricing Agreements could have imagined that petitioners could face such an onslaught of burdensome and unpredictable litigation. Such litigation will harm the public interest by embroiling both Medicaid and the 340B program in confusion and uncertainty, if not outright inconsistent judicial directives. And

nothing in Congress's enactments provides any warrant for such litigation. For all these reasons, this Court should grant certiorari.

ARGUMENT

I. THE DECISION BELOW END-RUNS THIS COURT'S LIMITS ON IMPLIED PRIVATE RIGHTS OF ACTION.

A. The Ninth Circuit Fashioned A Federal Common Law Claim To Circumvent The Absence Of A Statutory Right Of Action.

The decision below is inconsistent with the entire thrust of four decades of this Court's jurisprudence concerning implied rights of action and related issues. In devising a private right of action in the *conceded absence* of a statutory right of action, the Ninth Circuit "revert[ed] in this case to the understanding of private causes of action that held sway 40 years ago." *Sandoval*, 532 U.S. at 287. It may once have been this Court's view that courts' duty was "to provide such remedies as are necessary to make effective the congressional purpose" reflected by a statute. *J.I. Case Co. v. Borak*, 377 U.S. 426, 433 (1964). But that view has long since been "abandoned." *Sandoval*, 532 U.S. at 287.

Since *Cort v. Ash*, 422 U.S. 66 (1975), this Court has consistently and with increasing vigor rejected judicial efforts to read remedies into federal statutes that Congress did not put there. *See, e.g., Sosa v. Alvarez-Machain*, 542 U.S. 692, 727 (2004); *Gonzaga Univ. v. Doe*, 536 U.S. 273, 285 (2002); *Sandoval*, 532 U.S. at 287-88; *Cent. Bank of Denver, N.A. v. First Interstate Bank of Denver, N.A.*, 511 U.S. 164, 173 (1994); *Touche Ross & Co. v. Redington*, 442

U.S. 560, 568 (1979). That restraint is more than a trend. It is a reflection of core separation of powers principles: Private rights of action to enforce federal law, like substantive federal law itself, must be created by Congress. *See Sandoval*, 532 U.S. at 286; *Touche Ross*, 442 U.S. at 578. A contrary view would amount to judicial encroachment on Congress's purview over the remedies available for violations of federal statutes. Today "it is settled that there is an implied cause of action only if the underlying statute can be interpreted to disclose the intent to create one." *Stoneridge Inv. Partners, LLC v. Scientific-Atlanta, Inc.*, 552 U.S. 148, 164 (2008).

The Court has applied these settled principles even in cases involving alleged *constitutional* violations. In *Correctional Services Corporation v. Malesko*, 534 U.S. 61 (2001), this Court declined to infer a *Bivens* damages remedy for alleged constitutional violations by a government contractor operating a halfway house. Citing *Sandoval*, the Court explained that it had "abandoned" the *Borak* understanding of private rights of action "decades ago" and "retreated from our previous willingness to imply a cause of action where Congress has not provided one." 534 U.S. at 67 n.3. The Court has only reinforced this reluctance to infer private statutory and constitutional rights of action since *Malesko*. *See, e.g., Wilkie v. Robbins*, 551 U.S. 537 (2007); *see also Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1948 (2009) ("implied causes of action are disfavored").

This Court has thus been clear and consistent: Absent congressional intent to create a cause of action, "a cause of action *does not exist* and courts

may not create one." *Sandoval*, 532 U.S. at 286-87 (emphases added). Other courts of appeals have correctly grasped and applied that message. *See Grochowski v. Phoenix Constr.*, 318 F.3d 80, 86 (2d Cir. 2003); *Hodges v. The Atchison, Topeka & Santa Fe Ry. Co.*, 728 F.2d 414, 416 (10th Cir. 1984); *Hoopes v. Equifax, Inc.*, 611 F.2d 134, 135 (6th Cir. 1979); *cf. Buck v. Am. Airlines, Inc.*, 476 F.3d 29, 37 (1st Cir. 2007) (refusing "to abet a blatant evasion of the implied right of action doctrine" through state-law mechanisms).

The Ninth Circuit, in contrast, created a private cause of action here despite conceding that the statute did not. The court below lost sight of the fundamental point that whether a cause of action exists turns on whether Congress created one. The court concluded that "[a]lthough the statute mandating the [Pharmaceutical Pricing Agreement] does not create a federal private cause of action, allowing [respondent's] contract claim to go forward is consistent with Congress' intent in enacting the legislative scheme." Pet. App. 29a. That is a non-sequitur. If Congress had intended to create the claim that respondent seeks to bring, it would have provided an express cause of action. Congress did not enact such a cause of action, and the courts lack the authority to create it. *See Sandoval*, 532 U.S. at 286-87.

This Court did not take pains to articulate and reinforce these limits in decisions like *Sandoval*, *Stoneridge*, and *Malesko* just so the lower courts could nullify their practical effect by a simple resort to federal common law. If the decision below is correct, the analysis of whether a federal statute

creates a private damages action is largely academic; the conclusion that there is no statutory cause of action simply clears the way for the recognition of a federal common law cause of action. This gets matters backwards. This Court has, if anything, been more clear that the resort to the federal common law is disfavored. *See, e.g.*, *O'Melveny & Myers v. FDIC*, 512 U.S. 79, 87 (1994). Indeed, federal common law is a uniquely poor source of authority to trump the remedies determination made by Congress. While it remains a slight overstatement that "[t]here is no federal general common law," *Erie R. Co. v. Tompkins*, 304 U.S. 64, 78 (1938), any residual common-law authority in the federal courts is limited and "subject to the paramount authority of Congress," *Nw. Airlines, Inc. v. Transp. Workers Union of Am.*, 451 U.S. 77, 95 (1981). Because the federal common law authority is strictly limited, lower courts should be doubly loath to use that disfavored device to fashion the disfavored remedy of an implied damages action to enforce a federal statute and evade this Court's precedents. But that is precisely what the Ninth Circuit accomplished in the decision below.

B. The Ninth Circuit Erred By Creating A Damages Remedy Based On Its View Of The Policies At Issue.

The Ninth Circuit's decision appears to have been based on that court's view that the 340B statutory scheme does not provide adequate enforcement measures and thus that it was "sensible" to enlist 340B entities to assist the Government with enforcement. *See* Pet. App. 27a.

The Ninth Circuit emphasized that the 340B statute "does not 'expressly provide' any remedies to covered entities." Pet. App. 25a. And it suggested that HHS's authority to enforce the 340B program requirements against manufacturers was less than robust. *See* Pet. App. 26a. The court thus viewed empowering respondent as a private attorney general as "one way of ensuring that drug companies comply with their obligations," rather than "'plac[ing] the entire burden of enforcement' on the government." Pet. App. 27a (quoting *Price v. Pierce*, 823 F.2d 1114, 1121 (7th Cir. 1987)).

The Ninth Circuit's approach was wholly misplaced. The determination of how to structure a proper enforcement scheme is for Congress. The courts' job is to ascertain the remedies that Congress created. It is not to second-guess or try to improve upon Congress's judgment armed with nothing more than federal common law and a view of what is "sensible." *See Sandoval*, 532 U.S. at 286-87. In emphasizing that Congress had not provided any express remedies to 340B entities, the court below seemed motivated by a sense that *some* remedy *must* exist. But the absence of a statutory remedy is a rational determination, not an invitation for supplementation via federal common law. "Indeed, it is where Congress has intentionally withheld a remedy that we must most refrain from providing one because it is in those situations that 'appropriate judicial deference' is especially due . . . ." *Wilson v. Libby*, 535 F.3d 697, 709 (D.C. Cir. 2008) (quoting *Schweiker v. Chilicky*, 487 U.S. 412, 423 (1988)), *cert. denied*, 129 S. Ct. 2825 (2009).

The Ninth Circuit failed to recognize two critical facts that in the *Bivens* context would be called "special factors counseling hesitation." First, in examining the statutory remedies specific to the 340B program *in isolation*, the Ninth Circuit failed to recognize that the 340B program is inextricably linked to the Medicaid rebate program. AMP and BP were created under the Medicaid rebate program before the 340B program existed. They continue to be determined under that program and then simply carried over to serve the 340B program. Accordingly, the strength of the statutory remedies specific to the 340B program is largely beside the point as a practical matter, because the Medicaid rebate program is indisputably subject to vigorous enforcement by the Government. *See* U.S. CA9 Br. 28. Congress' decision not to create a private right of action for 340B entities was perfectly sensible because those entities in effect piggyback on the work done in the Medicaid rebate program to establish the prices used in the 340B program. There was and is no need for a separate mechanism, specific to the 340B program, to duplicate the enforcement structure in place to police compliance with Medicaid.

Second, in fashioning a federal common law remedy for third-party beneficiaries of government contracts, the Ninth Circuit ignored the existence of a wholly separate statutory regime designed to address the government contracts field: the False Claims Act ("FCA"). The FCA expressly creates a private right of action for damages, and quite a powerful one at that. Anyone can sue as a "relator" in the name of the United States, even without suffering individual injury. *See Vt. Agency of Nat.*

Res. v. U.S. ex rel. Stevens, 529 U.S. 765 (2000). The FCA provides for penalties on top of treble damages. 31 U.S.C. § 3729(a). Prevailing relators collect up to 30% of the "proceeds of the action or settlement" as a bounty, plus their attorney's fees. *Id.* § 3730(d)(2). The Government has obtained *billions* of dollars under the FCA in recent years. *See* U.S. Dep't of Justice, *Fraud Statistics*, http://www.justice.gov/opa/pr///fraud-statistics1986-2008.htm.

The point is not that respondent has a valid FCA remedy. If respondent could comply with all the demands of the FCA, including Fed. R. Civ. P. 9(b)'s particularized pleading standard for fraud and § 3729(b)(3)'s demanding standard for scienter, it presumably would be pursuing the treble damages remedy provided by Congress.[2] Rather, the point is that when Congress has enacted a statutory scheme to ensure fair dealing in contractual undertakings with the Government — especially one that allows non-contracting parties to sue in certain specifically designated situations, subject to specific limits — there is no role for a federal court to augment that

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[2] Respondent initially sued petitioners under California's False Claims Act, which tracks the federal FCA. *See* Pet. App. 99a-100a, 105a. After the district court dismissed the state FCA claim, respondent devised its third-party beneficiary theory and added a breach of contract claim. *See* Pet. App. 100a. After the district court held that respondent could not satisfy Fed. R. Civ. P. 9(b) and dismissed the state FCA claim a second time, respondent abandoned that claim. *See* Pet. App. 7a. Respondent has not acquired a more substantial basis for its claims as this litigation has extended into its sixth year and consumed extensive resources; the court below recognized that "the nature of the breaches [respondent] will seek to prove is unclear." Pet. App. 29a.

system by authorizing third-party beneficiaries to bring common law actions. The creation of federal common law is not simply disfavored, *see O'Melveny & Myers*, 512 U.S. at 87, but entirely inappropriate when an express cause of action occupies the field.

Finally, the Ninth Circuit's insistence that empowering 340B entities to sue will "help" the Government is mystifying. The Government, in response to the court's request, explained its view that "permitting [respondent's] challenge would conflict with Congress's comprehensive administrative and enforcement scheme, and accord [respondent] contract rights never intended by the PPA's signatories." U.S. CA9 Br. 13. It is remarkable enough that the court below believed that it knew better than the Government whether federal common law enforcement by 340B entities would be a "sensible" bolstering of the Government's enforcement authorities. *See* Pet. App. 27a. But it is truly astonishing that the court reached that conclusion without so much as mentioning the Government's statement that "HHS never imagined that a 340B entity could bring a third-party beneficiary lawsuit like [respondent's]." U.S. CA9 Br. 21.[3]

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[3] It goes without saying that drug manufacturers, the other parties to the PPA, also never "intended to grant covered [340B] entities enforceable rights" or foresaw third-party beneficiary litigation of this type. *See* Pet. App. 13a.

II. THE DECISION BELOW WILL UNDERMINE THE REGULATORY SCHEME.

In addition to running counter to this Court's recent jurisprudence, the Ninth Circuit's decision will have sweeping ramifications on the regulatory scheme. While the Ninth Circuit suggested that the "ceiling prices" charged by drug manufacturers to 340B entities escape all oversight, the reality is far different. Manufacturers are required by law to report to HHS the two core components of the 340B ceiling price — AMP and BP. And HHS has the authority — the *exclusive* authority — to audit those reported price components. The regulatory scheme thus not only provides a mechanism for oversight of 340B ceiling prices, but it squarely delegates oversight responsibility to HHS. Congress correctly recognized that HHS is uniquely equipped to navigate the technical complexities of drug pricing, make reasonable policy judgments, balance competing interests, and impose uniform standards. By inviting the courts into the determination of AMP and BP at the behest of purported third-party beneficiaries, the decision below threatens far-reaching uncertainty, disuniformity, and destabilization.

A. Private Enforcement Upends HHS's Exclusive And Expert Oversight Over The 340B Ceiling Price Components.

The 340B ceiling price is calculated from a formula based on the two inputs challenged by respondent — AMP and BP. Both inputs are part of the detailed Medicaid regulatory scheme. Congress requires drug manufacturers to report AMP and BP

at specified intervals to CMS as part of the Medicaid outpatient drug rebate program. *See* 42 U.S.C. § 1396r-8(b)(3)(A). Congress has also directed HHS to promulgate regulations offering guidance on how to calculate AMP. *See* Pub. L. No. 109-171, § 6001(c)(3)(B); 42 C.F.R. §§ 447.500-447.520. Moreover, Congress has supplied HHS with various enforcement tools to audit and investigate manufacturers' reported AMP and BP figures. *See* 42 U.S.C. § 1396r-8(b)(3)(A)-(B). HHS may levy monetary penalties if the figures are untimely or false, *see id.* § 1396r-8(b)(3)(B)-(C), or work with the Department of Justice to pursue False Claims Act remedies. *See id.* § 1396r-8(b)(3)(C)(ii). And HHS can impose the ultimate sanction — it can terminate the manufacturer's eligibility for Medicaid for good cause. *See id.* § 1396r-8(b)(4)(B).

The Ninth Circuit examined only the authorities created by the 340B statute itself, *see* Pet. App. 25a-27a, and its apparent belief that the 340B statute does not give HHS robust enforcement authorities thus misses the point. AMP and BP originated in the Medicaid rebate program before the 340B program was created in 1992. AMP and BP are determined and reported to CMS under the Medicaid rebate program. The ceiling price for the 340B program simply borrows these inputs from Medicaid. The Government's amicus brief explained that "[b]y focusing on [the Health Resources and Services Administration] and the 340B statute, [respondent] ignores the important role that CMS and the Social Security Act play in the 340B Program." U.S. CA9 Br. 27. Although respondent is a 340B entity rather than a state Medicaid agency, "to the extent that [respondent] is challenging

manufacturers' AMP and Best Price calculations, [respondent] is actually challenging figures reported to CMS as part of the Medicaid Rebate Program." *Id.* And the Government explained that, whatever may be the case with respect to the 340B program and HRSA in isolation, the Medicaid rebate program "has clearly been committed to CMS's comprehensive regulatory authority." *Id.*

As noted, however, the Ninth Circuit did not address the substance of the Government's amicus brief, and it made the same error as respondent by failing to recognize that CMS's oversight of the Medicaid rebate program amounts to oversight of the calculation of the 340B ceiling price. For the same reason, the court below failed to understand that the use of Medicaid pricing inputs in the 340B program means that "allowing suits like this would threaten the orderly operation of *both* programs." *Id.* at 19 (emphasis in original). Simply put, if a court orders a manufacturer to calculate AMP or BP in a particular way at the instance of a 340B entity, that same calculation will necessarily apply in the Medicaid rebate program. *See* 42 U.S.C. § 256b(b). There can only be one AMP and BP at a time for a given drug.

B. Private Enforcement Will Generate Confusion And Conflicting Standards.

Private enforcement of the 340B program that aims to test its AMP and BP components cannot function in practice.

As an initial matter, the scope of the programs and operations implicated by this suit is massive. Approximately 150 innovator drug manufacturers

determine and report BP every calendar quarter for more than 6,300 drug products. These manufacturers and many more calculate and report AMP every month *and* every quarter for over 25,000 products. For each dosage form and strength of an innovator prescription drug, a manufacturer must therefore report four BPs and 16 AMPs every year. Many PhRMA members calculate and report over 50 of these Medicaid price points each reporting period. In 2003, drug manufacturers paid out over $6.5 billion in Medicaid rebates; 340B discounts in the same period totaled approximately $600 million.[4] The effect of AMP and BP in the Medicaid rebate program is thus an order of magnitude larger than in the 340B program.

The litigation burdens imposed by respondent's claims are staggering. Respondent challenges all AMPs and BPs reported by nine large manufacturers over the course of seven and a half years. *See* Pet. App. 74a. This claim implicates more than five thousand separate prices reported to CMS for hundreds of drug products. To support its allegation that petitioners overcharged it in unspecified ways, respondent seeks "[a]ll information . . . underlying [petitioners'] determinations of AMP and BP." *Id.* This, moreover, is but the "first stage of discovery." *Id.* Respondent then will have 40 pages to frame the additional discovery that it will seek at "Stage Two." Pet. App. 77a. If the decision below is permitted to stand, the entire industry will be subjected to

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[4] In 2009, the U.S. pharmaceutical and biotechnology industries paid out over $8.3 billion in Medicaid drug rebates.

disruptive and extraordinarily expensive third-party beneficiary fishing expeditions for years to come.

As burdensome as such litigation will be for manufacturers, the burden alone is not the worst problem. Private litigation also will generate uncertainty and inconsistency that will make ongoing compliance with Medicaid rebate program obligations nearly impossible. Determining AMP and BP is extremely complex and technical. The figures are calculated in dollars to six decimal places — to one *ten-thousandth* of a penny. Manufacturers have entire departments devoted to the calculation of government-reportable prices. They enlist expensive and sophisticated computer systems to track sales, customers, adjustments, discounts, rebates, price concessions, and other data just for this purpose. Manufacturers also employ legal and compliance officers trained specifically in the administration of pricing reporting requirements, who issue and oversee detailed internal policies and procedures. HHS is far better equipped to grasp and navigate these complexities than courts equipped only with federal common law.

Manufacturers must try to interpret ambiguous program requirements, often without clear (or any) HHS guidance. For example, manufacturers are required to allocate so-called "bundled" discounts across affected products. Yet important questions about what kinds of arrangements actually constitute bundles and how the attendant price concessions are to be allocated in practice remain unanswered and largely uncommented upon. Where HHS has yet to issue guidance on a specific interpretive issue, preserving the exclusivity of

HHS's oversight takes on even greater importance. HHS instructs that in such a situation, the manufacturer "may make reasonable assumptions in its calculations" of AMP and BP. Medicaid Drug Rebate Agreement § II(i). A "reasonable" assumption cannot be distinguished from an "unreasonable" one without specialized expertise and a deep understanding of the industry. And coherent guidance as to the proper treatment of ambiguous issues can only emerge if there is a single interpreter. HHS possesses that expertise and understanding, and HHS is the only entity in a position to provide uniform and definitive answers.

The Government itself has not yet come close to definitively resolving all the difficult questions that can arise in calculating AMP and BP. The tacit premise of respondent's claim appears to be that AMP and BP are governed by simple formulae, but that is very far from the truth. As the Government explained in the court below, "manufacturers must contend with many difficult issues of interpretation, including questions surrounding the definition of a 'wholesaler,' questions about the meaning of 'retail class of trade,' and questions about a variety of complex pricing arrangements." U.S. CA9 Br. 4-5. The broad definitions in the Medicaid rebate statute and the agreements thereunder raise as many questions as they answer. CMS has issued "Releases" containing ad hoc guidance over the years, but those Releases did not purport to provide comprehensive instructions. *See* U.S. CA9 Br. 5. There were no regulations from the 1991 inception of the program until 2007. *See* 72 Fed. Reg. 39,142 (July 17, 2007). Although the 103-page preamble and regulations published in 2007 went some

distance toward clarifying matters, they left significant interpretive issues and practical complexities unaddressed. *See* U.S. CA9 Br. 29 ("even working within CMS guidance, a number of difficult interpretive questions can arise"). And now the health care reform bills enacted in March 2010 have raised many new questions.

But if the issues are left to HHS, there is at least the possibility of clear answers ultimately emerging. The agency can provide guidance and the agency's position could be tested, subject to appropriate deference, under the APA. Under the Ninth Circuit's approach, every one of these unanswered details would be the subject of litigation. With courts guided by nothing more than the federal common law and their own conception of what is sensible, inconsistent rulings are certain to emerge.

But this is not a program where uncertain and inconsistent results can be tolerated. There can only be one AMP and one BP, applicable to both the 340B program and Medicaid. There cannot be different AMPs or BPs for a given drug in a given reporting period in different jurisdictions. This unitary, national system cannot be governed by multiple courts issuing disparate orders about how to determine these price points. Even where the court orders are not diametrically opposed — one court holding that sales to specialty pharmacies are included in AMP, and another court holding the opposite — it suffices for the orders to be even slightly different to destroy the nationwide uniformity on which these programs are premised. Given the wide scope for judgment calls in gray areas, it would not take much litigation to produce

different judicially-approved methodologies that would make nationwide uniformity impossible. Court orders arising out of this kind of litigation might also contradict CMS guidance, making simultaneous compliance with judicial and executive pronouncements impossible and putting drug manufacturers in an untenable bind.

In short, the reality of AMP and BP dictates flexibility and reliance on HHS's unique, centralized expertise. The type of mass litigation pursued by respondent, in contrast, presumes that if only manufacturers are dragged through enough discovery, 340B entities and courts will be able to ascertain the "correct" figures and that any departure from those figures reflects a breach of contract. Once the regulatory scheme is understood, however, it is crystal clear that opening the door to private enforcement through damages actions is not at all compatible with the orderly operation of either the 340B program or the Medicaid rebate program. The Ninth Circuit was able to declare that recognizing a federal common law claim was "wholly compatible with the Section 340B program's objectives," Pet. App. 26a, only because it did not address the Government's explanation of how the 340B program takes its pricing inputs from the Medicaid rebate program such that "allowing suits like this would threaten the orderly operation of *both* programs." U.S. CA9 Br. 19 (emphasis in original).

C. States And 340B Entities Have Conflicting Interests That Further Undermine The Ninth Circuit's Simplistic Model Of Third-Party Beneficiary Suits.

The Ninth Circuit's notion that 340B entities are the intended beneficiaries of the 340B contracts fails to appreciate the complexity of the regulatory regime generally and the interrelationship between the Medicaid rebate program and the 340B program in particular. The Government uses AMP both to set the amount manufacturers must pay in Medicaid rebates to States and to establish the 340B ceiling price that may be charged to 340B entities. The interests of States and 340B entities in this respect are often directly opposite. In most circumstances, the lower the AMP, the lower a product's price to a 340B entity. Conversely, in most circumstances, the higher the AMP, the more a state Medicaid agency receives in rebates from manufacturers. On the myriad issues for which there is no definitive statutory or regulatory guidance, 340B entities will advocate an interpretation that reduces AMP, while States will advocate an interpretation that increases it.

Thus, this is not a simple matter where the Government insists on a provision in a contract for the exclusive benefit of an identifiable third party. The critical pricing metrics that respondent seeks to attack are not designed for 340B entities' benefit, but are the product of a more complicated regulatory system that serves multiple ends. Resolution of the competing demands in that complex program should be undertaken deliberately by the political branches.

It should not be displaced by a crazy-quilt of judicial decisions driven by a race to litigate.

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The Ninth Circuit recognized that the relevant statute did not provide an express cause of action. Rather than accept the consequences of Congress's decision not to authorize private damages actions and follow this Court's lead in swearing "off the habit of venturing beyond Congress's intent," the Ninth Circuit could not resist respondent's "invitation to have one last drink." *Sandoval*, 532 U.S. at 287. That decision would merit correction even if the decision did not threaten immediate and severe disruption to important health care programs. The scale and immediacy of the harm that the decision below will cause reinforces the need for this Court's review now.

CONCLUSION

The petition for a writ of certiorari should be granted.

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