NO. 09-1273

In the
Supreme Court of the United States

ASTRA USA, INC., ET AL.,
PETITIONERS,
v.
COUNTY OF SANTA CLARA,
RESPONDENT.

On 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, affiliates, and research associates). PhRMA advocates 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. In support of that mission, PhRMA members invested approximately $45.8 billion (of an industry total of approximately $65.3 billion) in 2009 in the discovery and development of new medicines. *See* 2010 Industry Profile, http://www.phrma.org/profiles_and_reports.

PhRMA monitors legal issues and cases that have significant impact on the pharmaceutical industry. To that end, PhRMA regularly files briefs in cases before this Court. *See, e.g.*, *Merck & Co., Inc. v. Reynolds*, 130 S. Ct. 1784 (2010) (No. 08-905); *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006) (No. 05-130).

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[1] Pursuant to Rule 37.6, *amicus* states that no counsel for any party authored this brief in whole or in part, and that no person or entity other than *amicus* or its counsel made a monetary contribution to the preparation or submission of this brief. The parties have consented to the filing of this brief, and letters evidencing such consent have been filed with the Clerk pursuant to Rule 37.3.

The decision below has sweeping and unsettling consequences for pharmaceutical companies and the federal drug programs in which they participate. The Ninth Circuit armed 340B covered entities with a federal common law cause of action to sue drug manufacturers for alleged overcharges on the theory that 340B entities are third-party beneficiaries of contracts between manufacturers and the Department of Health and Human Services ("HHS"). Neither party to these contracts intended that 340B entities would be able to bring such damages actions, and neither party could have imagined that result given that the 340B statute concededly does not create such a right of action. The decision means that by entering into contracts with HHS to provide deep discounts or rebates on drugs purchased by the Nation's safety net providers, drug manufacturers subjected themselves unwittingly to unprecedented damages suits from the more than 14,500 entities that participate in the 340B program. In addition to the staggering litigation burdens posed by such suits, allowing non-statutory private damages suits in this complex and important field will undermine the uniformity and predictability that Congress sought to achieve by delegating the administration of the 340B program and the Medicaid rebate program to HHS.

INTRODUCTION AND SUMMARY OF ARGUMENT

It is now settled 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). In no uncertain terms, this Court has emphasized that it

long ago "abandoned" the view that the federal courts' role is to attempt to improve statutory schemes by creating remedies that Congress did not provide. *Id.* at 287. It is undisputed that the statute at issue here, section 340B of the Public Health Service Act, 42 U.S.C. § 256b, does not create a private right of action allowing 340B entities to challenge the calculation of statutory ceiling prices through suits against participating drug manufacturers. That should have been the end of the analysis.

For the Ninth Circuit, the lack of a cause of action in the statute was instead an entry point into a freewheeling analysis of whether creating a federal common law cause of action would be "sensible." The Ninth Circuit's approach ignored the fundamental thrust of this Court's implied rights of action jurisprudence for the past 40 years: Under our system of separated powers, it is the job of Congress, not the federal courts, to decide what remedies are warranted. Congress not only has the constitutional authority to enact law, but is well-positioned to envision and address subsidiary questions like the statute of limitations, the extent of secondary liability, the appropriate forum, and the like. The lack of a statutory cause of action is thus the dispositive fact under core separation of powers principles — not a technicality to be waved aside en route to consideration of what remedies the court thinks should exist. That the Ninth Circuit resorted to federal common law to fashion the private right of action that Congress withheld exacerbates the error. The role of federal common law in the post-*Erie* world is extremely limited. Invoking that disfavored source of law to evade this Court's precedents

disfavoring non-statutory causes of action is doubly erroneous.

For these reasons, this Court should hold that where a federal statute does not create a private right of action, courts may not use federal common law to create a cause of action to enforce that statute. That holding flows from basic separation of powers principles and does not depend on whether it would be "sensible" to fashion a non-statutory cause of action in a given context or, rather, whether doing so would undermine or conflict with the statutory scheme. The courts' role is to ascertain the remedies that Congress has actually created, not to second-guess the wisdom of Congress's decision not to enact explicit remedies.

The Ninth Circuit's error here, however, went far beyond a "harmless" or abstract violation of the separation of powers. Federal common law actions challenging manufacturers' reported 340B price components will undermine the proper operation of both the 340B program and the much larger Medicaid rebate program by causing confusion and inconsistency and interfering with HHS's ability to reconcile competing interests and make reasonable, expert policy judgments. Remarkably, HHS explained to the Ninth Circuit that "allowing suits like this would threaten the orderly operation of *both* programs," U.S. CA9 Br. 19 (emphasis in original), and yet the Ninth Circuit decided for itself that empowering 340B entities to sue would be "sensible" and would help the Government by easing its enforcement burden. Even more remarkably, the Ninth Circuit did so without pausing to address the Government's view.

In short, even if it were permissible to create a federal common law claim to allow a purported third-party beneficiary to enforce some other statutory scheme, the statutory scheme at issue here cannot tolerate such judicial improvisation. The decision below does not merely conflict in theory with a presumed congressional intent; it promises direct, immediate, and far-reaching disruption of two vast and complex regulatory programs that Congress created. This Court therefore should reverse the decision below on any understanding of the authority of the federal courts to create federal common law claims to enforce federal statutes.

ARGUMENT

I. COURTS MAY NOT CREATE PRIVATE RIGHTS OF ACTION TO ENFORCE STATUTES THAT DO NOT CREATE PRIVATE RIGHTS OF ACTION.

A. This Court's Precedents Prohibit Fashioning A Private Cause Of Action That Congress Has Not Provided.

The Ninth Circuit's decision "revert[s] …to the understanding of private causes of action that held sway 40 years ago." *Alexander v. Sandoval*, 532 U.S. 275, 287 (2001). In a long line of authority since *Cort v. Ash*, 422 U.S. 66 (1975), this Court has consistently and ever more emphatically repudiated the approach of *J.I. Case Co. v. Borak*, 377 U.S. 426 (1964). The guiding principle of the *Borak* era was that it was "the duty of the courts to be alert to provide such remedies as are necessary to make effective the congressional purpose." *Id.* at 433. The courts have long since gone off alert. *See Sandoval*,

532 U.S. at 175 ("We abandoned that understanding … and have not returned to it since.").

In case after case, this Court has rejected judicial efforts to infer private rights of action and remedies where the statute provides no cause of action. *See, e.g.*, *Sosa v. Alvarez-Machain*, 542 U.S. 692, 727 (2004); *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); *Mass. Mut. Life Ins. Co. v. Russell*, 473 U.S. 134, 148 (1985); *Touche Ross & Co. v. Redington*, 442 U.S. 560, 568 (1979). The Court has rebuffed appeals to generalized "remedial purposes" of statutes as a way to go beyond or purport to improve upon statutory schemes as they were actually enacted. *See, e.g.*, *Touche Ross*, 442 U.S. at 578. And the Court has clarified over and over again that the "ultimate issue" is whether Congress created the asserted right or remedy. *Sierra Club*, 451 U.S. at 293; *see also Va. Bankshares, Inc. v. Sandberg*, 501 U.S. 1083, 1102 (1991) ("recognition … must ultimately rest on congressional intent to provide a private remedy"); *Nw. Airlines, Inc. v. Transport Workers*, 451 U.S. 77, 91 (1981) ("ultimate question … is whether Congress intended to create the private remedy"); *Transamerica Mortg. Advisors, Inc. v. Lewis*, 444 U.S. 11, 15 (1979) ("what must ultimately be determined is whether Congress intended to create the private remedy"); *Touche Ross*, 442 U.S. at 578 ("ultimate question is one of congressional intent"). Rather than assuming the authority to decide what remedies are necessary or appropriate, federal courts now must limit themselves to ascertaining what remedies Congress created.

What was already "clear" in 1979, *Touche Ross*, 444 U.S. at 16, is pellucid in 2010: 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). Unless Congress intends 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.

These are not merely scattered or fact-bound decisions. They reflect instead fundamental separation of powers limits on the authority of the federal courts. Where a court recognizes a private right of action in the absence of congressional intent, it "'necessarily extends its authority to embrace a dispute Congress has not assigned it to resolve.'" *Stoneridge*, 552 U.S. at 164 (quoting *Am. Fire & Cas. Co. v. Finn.*, 341 U.S. 6, 17 (1951)); *see also Touche Ross*, 442 U.S. at 579 ("[W]e are not at liberty to legislate…. 'It is not for us to fill any *hiatus* Congress has left in this area.'") (citation omitted). As this Court has emphasized, the "decision to extend [a] cause of action is for Congress, not for us." *Stoneridge*, 552 U.S. at 165. Whether the court believes that Congress has made wise decisions about whether or how to extend a cause of action, or whether the court believes that it could improve upon the congressionally-enacted scheme, are simply not proper questions for the federal courts to ask.

This reluctance reflects not just the reality that only Congress has the constitutional authority to enact laws. It also reflects the practical reality that when Congress does actually enact a private cause of action, it generally explicitly anticipates and addresses subsidiary questions such as the statute of

limitations and the degree of secondary liability. When courts infer a cause of action that Congress has not expressly enacted, the courts cannot announce the appropriate statute of limitations or degree of secondary liability. Those issues must be resolved in subsequent cases based on default rules, because there is no clear congressional guidance on questions such as how long Congress would have wanted the statute of limitations to run for a cause of action it did not envision at all. In the Rule 10b-5 context, this Court has had to address the statute of limitations as a default matter, *Lampf, Pleva, Lipkind, Prupis & Petigrow v. Gilbertson*, 501 U.S. 350 (1991), then consider the constitutionality of Congress's effort to respond, *Plaut v. Spendthrift Farm, Inc.*, 514 U.S. 211 (1995), and had to consider the extent of secondary liability not once, *Cent. Bank of Denver, supra*, but twice, *Stoneridge*, *supra*.

In keeping with the fundamental nature of the limits on judicial authority to create non-statutory rights of action, this Court has adhered to this restrained approach in a variety of contexts. For example, even where *stare decisis* has left older decisions recognizing implied rights of action in place, the Court has consistently applied the modern rules to questions about the extension or application of those rights of action. *See, e.g., Stoneridge*, 552 U.S. at 165 ("Though it remains the law, the § 10(b) private right should not be extended beyond its present boundaries.").

The Court has also extended the principle beyond the statutory context to cases involving alleged constitutional violations. In *Correctional Services Corporation v. Malesko*, 534 U.S. 61 (2001), a federal inmate sought a *Bivens* damages remedy

against a government contractor running a halfway house. Emphasizing that the Court had "'abandoned' the view of *Borak* decades ago" and disavowed any "previous willingness to imply a cause of action where Congress has not provided one," the Court declined to create a *Bivens* remedy. *Id.* at 67 n.3, 70. In the years since *Malesko*, the Court has further reinforced that reluctance to extend *Bivens* remedies. *See Wilkie v. Robbins*, 551 U.S. 537, 562 (2007) (damages remedy "may come better, if at all, through legislation" rather than *Bivens*); *cf. Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1948 (2009) ("implied causes of action are disfavored").

Moreover, the Court has applied the same separation of powers principles in deciding which federal statutes are enforceable in private damages suits brought under 42 U.S.C. § 1983. *See Gonzaga Univ. v. Doe*, 536 U.S. 273, 290 (2002) ("if Congress wishes to create new rights enforceable under § 1983, it must do so in clear and unambiguous terms — no less and no more than what is required for Congress to create new rights enforceable under an implied private right of action").

Despite this clear and consistent precedent, the Ninth Circuit viewed the conceded lack of a statutory private right of action to enforce the 340B statute as an invitation to judicial creativity, rather than as the end of the analysis. *See* Pet. App. 22a (acknowledging respondent's concession that "there is no private federal cause of action under § 256b," the 340B statute). The Ninth Circuit noted that drug manufacturers' statutory drug pricing obligations are incorporated by reference in Pharmaceutical Pricing Agreements ("PPAs") — form contracts between HHS and the manufacturers

participating in the 340B program. And it held that although the 340B statute afforded no such action, 340B entities could bring breach-of-contract claims, as third-party beneficiaries of the PPAs under federal common law, to enforce the statutory requirements that manufacturers provide appropriate discounts to 340B entities.

In so holding, the Ninth Circuit openly appealed to what it viewed as the purposes of the 340B statute and "sensible" enforcement policy. Lamenting what it perceived as a "paucity of statutory authority" to enforce pricing obligations against drug manufacturers, the Ninth Circuit reasoned that allowing 340B entities to sue as third-party beneficiaries of the PPAs presented "one way of ensuring that drug companies comply with their obligations under the program." Pet. App. 26a-27a. Private suits, it suggested, were a "'sensible'" alternative to placing the entire "'burden of enforcement'" on HHS, *id.* (quoting *Price v. Pierce*, 823 F.2d 1114, 1121 (7th Cir. 1987)), and would be "compatible" with the statutory scheme. Pet. App. 26a.[2]

This approach harkens back to the discredited view of *Borak* that courts may create private rights of action based on nothing more than their own view of what might generally advance purposes reflected

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[2] The Ninth Circuit could assert that it was helping the Government by lightening its enforcement burden only because it ignored the Government's *amicus* brief explaining that the Government did not want any such "help" and that private common law suits "would conflict with Congress's comprehensive administrative and enforcement scheme." U.S. CA9 Br. 13.

in the statutory scheme. As explained in the next section, such a private right of action is not at all "compatible" with the 340B program (or the Medicaid rebate program to which the 340B program is inextricably linked), *see infra* at 18-27, but the proper question is whether Congress created such rights of action, not whether they are compatible with what Congress intended. *Sandoval*, 532 U.S. at 286-87 (absent statutory cause of action, "courts may not create one, no matter how desirable that might be as a policy matter, or how compatible with the statute").

Moreover, the Ninth Circuit's reasoning that "[a]lthough the statute … does not create a federal private cause of action, allowing Santa Clara's contract claim to go forward is consistent with Congress' intent," Pet. App. 29a, is a non-sequitur. If "Congress' intent" had been to permit such a cause of action, Congress would have created it. The conceded failure by Congress to create a private cause of action in the 340B statute is a clear indication that "Congress' intent" was *not* to create such a cause of action. *See Wilson v. Libby*, 535 F.3d 697, 709 (D.C. Cir. 2008) ("it is where Congress has intentionally withheld a remedy that we must most refrain from providing one"), *cert. denied*, 129 S. Ct. 2825 (2009). Yet the Ninth Circuit treated the absence of statutory remedies as a reason why it was necessary to conjure a new remedy through federal common law. *See* Pet. App. 25a (lamenting that the 340B statute "does not 'expressly provide' any remedies to covered entities"). In refusing to allow the statutory scheme as actually enacted to slow it down, the Ninth Circuit turned back the clock on the past forty years of this Court's precedents.

B. The Limited Role Of Federal Common Law Post-*Erie* Does Not Include Circumventing This Court's Implied Rights Of Action Jurisprudence.

1. The Ninth Circuit's approach to federal common law would render this Court's carefully delineated limits on implied rights of action for naught. Calling an implied cause of action a federal common law action does not change the fundamental reality that the Ninth Circuit created a cause of action that Congress chose not to enact. 340B entities certainly do not care what label is put on their federal cause of action. It is quite a consolation prize to be told that although they cannot bring a statutory cause of action for damages to enforce the statutory pricing requirements, they may bring an action for the same relief, to enforce the identical statutory requirements (which the statute dictates be included in the PPAs between the companies and HHS), through the guise of the federal common law of contracts. This Court has not gone to great lengths to chart a new course concerning the role of the federal courts vis-à-vis Congress and the limits on implied rights of action only to have lower courts opt out of those separation of powers principles through the simple expedient of invoking federal common law.

2. That such circumvention is inappropriate is even clearer given the extremely limited role of federal common law in the post-*Erie* era. Although the statement in *Erie R. Co. v. Tompkins*, 304 U.S. 64, 78 (1938), that "[t]here is no federal general common law" remains an overstatement, the federal common law authority of the federal courts in the post-*Erie* world is extremely limited and, of course, is

subject to "'the paramount authority of Congress.'" *Nw. Airlines*, 451 U.S. at 95 (citation omitted). Federal common law is thus a uniquely poor candidate for a vehicle to defeat Congress's choices about what enforcement mechanisms to create in a statute.

Three aspects of the decision below aptly illustrate the dangers of the model of judicial circumvention through federal common law. First, the Ninth Circuit entirely ignored the Government's unambiguous warning that judicially-created private rights of action would *not* improve upon the 340B program's regulatory scheme. The Government, in fact, warned that permitting private damages suits "would conflict with Congress's comprehensive administrative and enforcement scheme" and stated with perfect clarity that "HHS never imagined that a 340B entity could bring a third-party beneficiary lawsuit like [respondent's]." U.S. CA9 Br. 13, 21. Yet the Ninth Circuit failed even to acknowledge the Government's position, highlighting that what it described as "sensible" supplementation of the regulatory scheme made "sense" to the court — and the court alone. *See* Pet. App. 27a.

Second, the Ninth Circuit failed to acknowledge the vigorous enforcement mechanisms governing the Medicaid rebate program, to which the 340B program is inextricably linked. Respondent alleges that manufacturers miscalculated or misreported 340B ceiling prices. But the two critical components of 340B ceiling prices — Average Manufacturer Price ("AMP") and Best Price ("BP") — derive directly from the Medicaid rebate program. AMP and BP, created under the Medicaid rebate program before the 340B program existed, are the key inputs to calculating

the rebates owed to States for covered outpatient drugs. *See* 42 U.S.C. §§ 1396r-8(c)(1)(A)-(C), 1396r-8(c)(3). AMP and BP are determined for use in the Medicaid rebate program and simply carried over to be used in the 340B program.

Viewed in context, then, Congress's decision not to create a private right of action for 340B entities makes eminent sense. The Medicaid rebate program has its own comprehensive enforcement scheme governing the calculation of AMP and BP that effectively serves to protect 340B entities. When Congress legislates concerning a complex statutory scheme, it can take the complex whole into account. A court confronted with a demand to create a new right of action in a particular case, in contrast, does not have the whole picture of the regulatory program or programs that might be affected by such a resort to federal common law. The Ninth Circuit's mistaken focus on the 340B program in isolation, divorced from the Medicaid rebate program, is a powerful demonstration of the risks in allowing ad hoc judicial determinations about what tinkering with complex statutory schemes is "sensible."

Third, the Ninth Circuit also ignored the existence of the False Claims Act ("FCA") — an express statutory cause of action designed precisely to ensure fair dealing in contractual undertakings with the Government. The FCA provides a highly potent private right of action for damages. Anyone can sue as a "relator" in the name of the United States, even without suffering individual injury. *See Vt. Agency of Natural Res. v. U.S. ex rel. Stevens*, 529 U.S. 765, 769 (2000). On top of treble damages, the FCA provides for penalties, and prevailing relators win up to 30% of the "proceeds of the action or

settlement" as a bounty, plus their attorney's fees. 31 U.S.C. §§ 3729(a), 3730(d)(2). Recoveries under the FCA in recent years have totaled in the billions. *See* U.S. Dep't of Justice, *Fraud Statistics*, http://www.justice.gov/opa/pr/2008/November/fraud-statistics1986-2008.htm. To be sure, respondent could not satisfy (*inter alia*) the demanding pleading or scienter standards set forth in Fed. R. Civ. P. 9(b) and § 3729(b)(3), respectively.[3] But an inability to satisfy the standards actually set by Congress is neither an invitation to nor a justification for judicial creation of a new claim.[4]

The critical point is that Congress has explicitly enacted a broadly applicable statutory cause of action that substantially overlaps with the federal common law action the Ninth Circuit created. The existence of that statutory cause of action not only belies the Ninth Circuit's suggestion that there was a void that needed filling. It also underscores Congress's manifest ability to enact powerful enforcement mechanisms in clear terms when it wishes to do so. Congress, in short, understands that it is responsible for creating private rights of action

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[3] Respondent initially brought a claim under California's FCA, which tracks the federal FCA, but abandoned it after the district court dismissed it twice. Having failed to satisfy the statutory standards, respondent then devised its third-party-beneficiary theory. *See* Pet. App. 7a, 99a-100a.

[4] Congress's specification of a heightened pleading standard and a demanding scienter requirement in the FCA is an illustration of the broader point that when Congress creates a cause of action, it can resolve important questions about the contours of that cause of action. A court inferring a private right of action from congressional silence cannot do so.

to enforce federal law, no less than it is responsible for enacting the underlying federal laws. *Sandoval*, 532 U.S. at 286. It unfairly and inappropriately disrespects Congress's constitutional role for a court to step in and create a non-statutory remedy on the rationale that Congress did not do its job.

3. The Patient Protection and Affordable Care Act ("PPACA"), enacted in March 2010, is a case in point illustrating the role of Congress, not the courts, to decide what enforcement mechanisms to create in the context of the specific programs at issue in this case. In the PPACA, Congress created a number of new 340B administrative enforcement mechanisms and lodged them within HHS, rather than creating a private right of action to authorize litigation directly in the courts. Three are of particular relevance. First, Congress directed HHS to establish a mandatory administrative process to resolve claims by 340B entities that manufacturers overcharged them — precisely the kind of claim at issue here. Pub. L. No. 111-148, § 7102(a), 124 Stat. 119 (2010) (adding 42 U.S.C. § 256b(d)(3)). Second, Congress empowered HHS to impose civil money penalties on drug manufacturers of up to $5,000 per instance of overcharging of a 340B covered entity. *Id.* (adding 42 U.S.C. § 256b(d)(1)(B)(vi)).[5] Third, Congress directed HHS to develop "a system to enable the Secretary to verify the accuracy of ceiling prices calculated by manufacturers … and charged to

[5] HHS solicited input from interested parties on September 20, 2010. 75 Fed. Reg. 57,233. The comment period concerning the mandatory dispute resolution and civil money penalties provisions closes on November 19, 2010.

covered entities." 42 U.S.C. § 256b(d)(1)(B)(i). The Secretary is charged with developing precise standards for the calculation of ceiling prices, comparing reported ceiling prices with those HHS calculates itself, performing spot checks on 340B sales transactions, and inquiring into the cause of reported pricing discrepancies. *Id.* Rather than validate respondent's approach and confer to juries across the Nation the task of resolving complex disputes about prices reported in these regulatory programs, Congress vested the resolution of those disputes in the expert agency, with the agency's decisions reviewable in court.

The PPACA reinforces that Congress has a broader range of potential remedies available to it than the courts have using the relatively blunt instrument of the federal common law. It also reinforces Congress's ability to address subsidiary issues like the proper forum, exhaustion, and the like. Congress's institutional competence and its careful attention to the precise issue here should dispel any notion that Congress needs or wants the courts' "help" in refashioning Congress's handiwork in ways the courts think seem sensible.

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For all these reasons, the decision below exemplifies why courts are poorly equipped to resort to federal common law in an effort to "improve upon the statutory scheme that Congress enacted into law." *Touche Ross*, 442 U.S. at 578; *see also Wilkie*, 551 U.S. at 562 ("'Congress is in a far better position than a court to evaluate the impact of a new species of litigation'") (citation omitted). When this Court pronounced that it had sworn "off the habit of

venturing beyond Congress's intent" when it comes to private rights of action and declined "to have one last drink," it surely did not intend to abandon all temperance if the label on the bottle were switched to the "federal common law." *Sandoval*, 532 U.S. at 287. This Court should not allow federal common law to become an escape hatch from this Court's precedents limiting non-statutory rights of action.

II. A PRIVATE RIGHT OF ACTION FOR 340B ENTITIES WOULD UNDERMINE THE STATUTORY SCHEME.

For the reasons just discussed, it violates fundamental separation of powers principles for a federal court to take it upon itself to supplement the remedies that Congress has created. When a statute does not create a private right of action, courts may not create one, whether under the rubric of implied statutory rights of action or federal common law. That fundamental limitation is true even where it would, in fact, be "sensible" as a policy matter to provide an additional remedy and the additional remedy under consideration would not undermine the statutory scheme. The Court thus should reverse the Ninth Circuit's decision even without any need to consider the intricacies of the 340B and Medicaid rebate programs or the sensibility of the Ninth Circuit's new federal common law remedy. In all events, however, this Court should reverse the decision below because it is clear that allowing third-party beneficiary damages claims would significantly undermine the orderly operation of the 340B and Medicaid rebate programs and that the federal common law right of action that the Ninth Circuit created is incompatible with the statutory scheme.

A. Private Damages Actions Would Undermine HHS's Exclusive And Expert Oversight Over The 340B Ceiling Price Components.

Arming 340B covered entities with private rights of action to enforce 340B ceiling prices against drug manufacturers would disrupt HHS's orderly administration of not one, but two major federal health care programs: the 340B program and the Medicaid rebate program. Congress made a deliberate decision to delegate to HHS the exclusive authority to audit manufacturers' reported AMPs and BPs. That this was Congress's deliberate decision should be sufficient, under basic separation of powers principles, to insulate it from judicial efforts at improvement. In the context of the programs at issue, moreover, Congress's decision to opt for orderly, expert administration by HHS rather than private damages actions by purported third-party beneficiaries was eminently sensible.

Respondent's claim is that nine drug manufacturers miscalculated the AMPs and BPs — the key components of 340B ceiling prices — of covered outpatient drugs, resulting in 340B entities in California being overcharged. As noted above, AMP and BP originated in the Medicaid rebate program, where they are the two critical inputs to calculating rebates owed to States for covered outpatient drugs. *See* 42 U.S.C. §§ 1396r-8(c)(1)(A)-(C), 1396r-8(c)(3). The 340B program merely carries over the AMP and BP from the Medicaid rebate program; indeed, the 340B program expressly incorporates the drug pricing provisions of the Medicaid rebate program. *See* 42 U.S.C. § 256b(a) (incorporating by reference 42 U.S.C. § 1396r-8).

Because AMP and BP continue to be calculated and reported pursuant to the Medicaid rebate program, the Ninth Circuit's apparent belief that the 340B statute gives HHS insufficiently robust enforcement authorities misses the point. As the Government explained in its *amicus* brief below, by "focusing on … 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. The Ninth Circuit, unfortunately, did not address and did not appear to consider the Government's explanation.

The Medicaid rebate program "has clearly been committed to [HHS's] comprehensive regulatory authority" through the Centers for Medicare & Medicaid Services ("CMS"). *Id.* The program sets forth a detailed regulatory scheme by which HHS maintains rigorous oversight of AMPs and BPs. The program obligates drug manufacturers to report AMP and BP at specified intervals to CMS. *See* 42 U.S.C. § 1396r-8(b)(3)(A). HHS enjoys exclusive authority to audit those reported AMPs and BPs. Congress has directed HHS to promulgate regulations offering guidance on how to calculate AMP correctly. *See* Pub. L. No. 109-171, § 6001(c)(3)(B), 120 Stat. 56 (2006); 42 C.F.R. §§ 447.500-447.520. Congress has supplied HHS with enforcement tools to investigate manufacturers' reported AMP and BP figures. *See* 42 U.S.C. § 1396r-8(b)(3)(A)-(B). Congress has also authorized HHS to impose monetary penalties if the reported price components are untimely or false, *see id.* § 1396r-8(b)(3)(B)-(C), or to pursue False Claims Act remedies through the Department of Justice. *See id.* § 1396r-8(b)(3)(C)(ii). And Congress has empowered

HHS to impose the ultimate sanction if manufacturers fail to submit reports, submit false information, or otherwise fail to comply with the Medicaid and 340B statute's requirements — it can terminate the manufacturer's eligibility for Medicaid. *See id.* § 1396r-8(b)(4)(B).

Viewing the 340B program in conjunction with the Medicaid rebate program, then, it is plain that HHS possesses and exercises comprehensive oversight authority of the 340B ceiling price components. In enacting this scheme, Congress recognized that HHS is uniquely equipped to handle the myriad technical issues involved in the calculation of AMP and BP, make reasonable policy judgments, and balance competing interests. In centralizing oversight in one agency, moreover, Congress understood pharmaceutical companies' need for uniform and predictable standards and the need for exclusive control by an expert agency if there is to be any hope of achieving uniformity and predictability.

The Ninth Circuit's creation of a federal common law right of action to litigate the proper calculation of AMP and BP radically undermines that regulatory scheme. Instead of a regime where HHS can bring to bear its expertise and make reasonable decisions about how to resolve the significant ambiguities and policy issues attendant to AMP and BP calculation in light of competing interests, juries across the Nation would render separate and likely inconsistent verdicts reflecting their views about how AMP and BP should be determined.

This invitation to inconsistency is incompatible with the very nature of the 340B and Medicaid

rebate programs and the role of AMP and BP in those programs. At any given time, there can only be one AMP and one BP for a drug. If a court decides at the behest of a 340B entity like respondent that a manufacturer should calculate AMP or BP in a specific way, that should control for the Medicaid rebate program. *See* 42 U.S.C. § 256b(b). If another court decides that AMP or BP should be calculated in even a slightly different way, manufacturers — and HHS — will face inconsistent mandates. And because the 340B and Medicaid rebate programs are conjoined, all the uncertainty and inconsistency that would result from private damages actions would affect both programs. That is why HHS warned that "allowing suits like this would threaten the orderly operation of *both* programs." U.S. CA9 Br. 19 (emphasis in original). The prospective remedy that Congress actually provided ameliorates these problems by funneling all decisions through the administrative process. That decision further underscores the imprudence of the Ninth Circuit's litigation-first approach.

B. Private Damages Actions By Thousands Of 340B Entities Are The Antithesis Of Uniformity And Predictability.

Congress's decision to delegate exclusive oversight over AMP and BP to HHS makes perfect sense given the highly technical nature of these drug pricing calculations and the critical need for uniformity. Determining AMPs and BPs is an intricate and complex enterprise occupying enormous resources. Approximately 150 innovator drug manufacturers determine and report BP every calendar quarter for more than 6,300 drug products. For over 25,000 products, these manufacturers and

others calculate and report AMP for each month *and* each quarter. Every manufacturer of an innovator prescription drug must report 16 AMPs and four BPs annually for every dosage form and strength of that drug. PhRMA members calculate and report many thousands of these Medicaid price points each year. And AMPs and BPs are determined with exacting precision to six decimal places — one ten-thousandth of a penny. Manufacturers devote vast amounts of resources to the determination and reporting of AMP and BP. They staff entire departments devoted to the calculation of accurate reportable prices. They install and maintain costly and advanced computer systems to track sales, customers, adjustments, discounts, rebates, price concessions, and hundreds of other data points. They also enlist legal counsel and compliance officers, trained specifically in price reporting requirements, to develop and issue detailed internal policies and procedures. They then employ sophisticated consulting firms to test their companies' performance against those procedures. Government price reporting is a high-risk, high-intensity, high-stakes proposition for every drug maker that markets a product in the United States.

Because of the scope of the 340B and Medicaid rebate programs, the impact of AMP and BP calculations is staggeringly high. In 2003, for example, 340B entities enjoyed over $600 million in discounts. Medicaid rebates amounted to an estimated $6.5 billion. The Court does not need to look further than this case to see how burdensome and inapt third-party beneficiary damages suits are in this unique context. Respondent challenges all AMPs and BPs reported by nine large manufacturers over nearly eight years, implicating over 5,000

separate prices reported to CMS and hundreds of drug products. *See* Pet. App. 74a. To support its bald allegation that petitioners overcharged it in unspecified ways, respondent seeks nothing less than "[a]ll information . . . underlying [petitioners'] determinations of AMP and BP." *Id.* And that is but the "first stage of discovery." *Id.*

The enormous burdens imposed by this judicially-minted right of action would be a good enough reason by themselves not to create this new species of claim. *Cf. Wilkie*, 551 U.S. at 561. The reality is far worse, however. The premise of respondent's claim is that there is a single correct way to determine AMP and BP and that, if only manufacturers are dragged through enough discovery, the correct calculation of AMP and BP, and manufacturers' departures from it, will reveal themselves. That premise is entirely incorrect. The determination of AMP and BP is rife with unresolved ambiguity and necessary judgment calls on technical and policy issues.

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. Uniform HHS guidance helps to alleviate many complexities that bedevil the creation of drug pricing methodologies by improving manufacturers' ability to understand what is needed to come into compliance with ambiguous statutory and regulatory requirements. To that end, CMS has issued "Releases" containing ad hoc guidance over the years. *See* U.S. CA9 Br. 5. The agency's position can thus be tested in courts, subject

to the appropriate deference under the Administrative Procedure Act.

Notably, however, even CMS, notwithstanding its unique expertise, often struggles to issue definitive guidance on thorny questions relating to AMP and BP calculations that simply do not have straightforward answers. The broad requirements of the Medicaid rebate statute and the often opaque terms of CMS sub-regulatory guidance raise a host of such difficult interpretive issues. For example, manufacturers are required to allocate so-called "bundled" discounts across affected products, but what arrangements actually constitute bundles and how attendant price concessions are to be allocated remain persistent sources of confusion and uncertainty. When the agency finally published regulations, along with a 103-page preamble, in 2007 — for the first time since the program's genesis in 1991 — the regulations offered significant clarifications, but left many complexities unanswered. *See* U.S. CA9 Br. 29. Existing CMS guidance and "Releases," then, do not purport to provide manufacturers with comprehensive instructions.[6]

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[6] In light of the PPACA's amendments to the Medicaid drug rebate statute, CMS has withdrawn its now-outdated regulatory definition of AMP. 75 Fed. Reg. 69,591 (Nov. 15, 2010) (withdrawing, *inter alia*, 42 C.F.R. § 447.504). CMS has stated that it "is committed to developing further regulations that will provide the necessary guidance to all parties impacted by the revisions made to the Medicaid Drug Rebate Program by the [PPACA]." *Id.* at 69,592-93. Until further guidance is issued, however, manufacturers face even greater uncertainty.

On questions as to which no specific CMS guidance yet exists, HHS's oversight responsibilities assume an even more critical role. HHS recognizes manufacturers' predicament and provides that under such circumstances, manufacturers are entitled to "make reasonable assumptions in [their] calculations of AMP and [BP]." Medicaid Drug Rebate Agreement § II(i), J.A. 78-79. Assigning those judgments to courts that are not steeped in the practical and technical issues involved in determining AMP and BP — and that are equipped with nothing more than the federal common law to make those judgments without meaningful guidance from Congress — is a recipe for rampant confusion and inconsistency.

In short, the federal common law "cure would be worse than the disease" that the Ninth Circuit sought to address. *Wilkie*, 551 U.S. at 561. Even if there could be some other regulatory context that could comfortably accommodate a judicially-created federal common law remedy, this is not it.

C. Conflicting Interests Between States And 340B Entities Exacerbate The Problems With The Decision Below.

Part of the reason drug pricing components require HHS's exclusive, uniform oversight is that the interrelationship between the Medicaid rebate program and the 340B program means that the interests of States and 340B entities often conflict. HHS 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. Typically, the lower the AMP, the lower a product's price to a 340B

entity. But the higher the AMP, the more a state Medicaid agency typically receives in rebates from manufacturers. Thus, 340B entities have an interest in resolving ambiguities and technical issues in ways that would reduce AMP, while States have the opposite interest. This dynamic makes Congress's decision to confer the operation of these programs to a centralized, expert agency even more prudent. HHS can ascertain competing interests and balance them in making reasonable policy judgments in a way that a court armed with nothing more than federal common law simply cannot. And the existence of competing interests in how AMP and BP are determined heightens the risk that private damages actions will lead to inconsistent results.

The Ninth Circuit wholly missed this bigger picture because of its mistaken focus on the 340B program in isolation. Misunderstanding AMP and BP as metrics intended exclusively to benefit 340B entities, the Ninth Circuit failed to grapple at all with the complexities posed by the conflicting interests of States and the operation of the Medicaid rebate program. That broader context makes it even clearer that federal common law damages actions would conflict with the way Congress intended these important regulatory programs to function. And the Ninth Circuit's error in failing to understand that broader context reinforces why courts should not undertake to decide whether supplementing a statutory scheme with a new remedy is or is not sensible.

* * * *

When Congress does not create a private right of action to enforce a statute, the consequence is not to

open the door to a freewheeling federal common law inquiry into the wisdom of the omitted relief. Rather, the consequence of Congress's decision not to create a cause of action to allow 340B entities to enforce the drug pricing agreements between manufacturers and HHS is that "a cause of action does not exist and courts may not create one." *Sandoval*, 532 U.S. at 286-87. This Court should reverse the Ninth Circuit's decision both because the court lost sight of that fundamental principle of our system of separated powers and also because its decision will gravely and concretely undermine the statutory scheme that Congress created to regulate drug pricing.

CONCLUSION

The decision below should be reversed.

Respectfully submitted,

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