No. 12-690

IN THE

Supreme Court of the United States

GLAXOSMITHKLINE LLC, ET AL.,
Petitioners,

v.

HUMANA MEDICAL PLANS, INC., ET AL.,
Respondents.

On Petition for a Writ of Certiorari
to the U.S. Court of Appeals
for the Third Circuit

BRIEF OF THE WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

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QUESTION PRESENTED

Whether the Medicare Secondary Payer Act, 42 U.S.C. § 1395y(b)(2), establishes a cause of action for private insurers operating Medicare Advantage plans to sue tortfeasors for double damages.

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INTERESTS OF *AMICUS CURIAE*[1]

The Washington Legal Foundation (WLF) is a public interest law and policy center with supporters in all 50 States. WLF devotes a substantial portion of its resources to promoting limited and accountable government, supporting the free enterprise system, and opposing frivolous and abusive civil litigation by the government and private litigants.

In particular, WLF has devoted substantial resources over the years to opposing efforts to create or imply new private rights of action that Congress never intended. WLF has appeared before this and other federal courts in numerous cases to espouse its view that if new federal causes of action are to be created, the impetus for doing show should come from Congress, not the courts. *See, e.g., Astra USA, Inc. v. Santa Clara County*, 131 S. Ct. 1342 (2011); *Sosa v. Alvarez-Machain*, 542 U.S. 692 (2004).

WLF is concerned that, if allowed to stand, the decision below will result in an explosion of unintended private litigation under Medicare Part C. WLF recognizes that federal courts have a responsibility, *in the absence of legislation*, to fashion federal remedies in cases raising issues of uniquely

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[1] Pursuant to Supreme Court Rule 37.6, *amicus curiae* WLF states that no counsel for a party authored this brief in whole or in part; and that no person or entity, other than WLF and its counsel, made a monetary contribution intended to fund the preparation and submission of this brief. More than ten days prior to the due date, counsel for WLF provided counsel for Respondents with notice of intent to file this brief. All parties have consented to the filing of this brief, and letters of consent have been lodged with the Court.

federal concern. But where, as here, Congress has adopted legislation that speaks to the issue at hand (whether the Medicare Secondary Payer Act provides Medicare Advantage organizations with a private cause of action for double recovery), there is no legal basis for recognizing a remedy that Congress never intended.

WLF has no direct interest, financial or otherwise, in the outcome of this case. It is filing this brief to promote the interests of the business community and the public at large. Because of its lack of direct interest, WLF believes that it can assist the Court by providing a perspective distinct from that of any party.

STATEMENT OF THE CASE

The Medicare Secondary Payer Act ("MSP Act") was enacted by Congress in 1980 in an effort to contain the costs of Medicare, a federally funded health-insurance program. Under 42 U.S.C. § 1395y(b)(2)(A), Medicare is considered a "secondary payer" to the extent that "payment has been made or can reasonably be expected to be made under a workman's compensation law or plan of the United States or a State or under an automobile or liability insurance policy or plan (including a self-insured plan) or under no-fault insurance." *Id.* But if these "primary payers" cannot "promptly" pay for services, Medicare may make payment, conditioned on

mandatory reimbursement by the primary payer. *See* 42 U.S.C. § 1395y(b)(2)(B)(i).[2]

To ensure mandatory reimbursement for Medicare by a primary payer, the MSP Act provides that "the United States may bring an action against any or all entities that are or were required or responsible . . . to make payment with respect to the same item of service (or any portion thereof) under a primary plan." 42 U.S.C. § 1395y(b)(2)(B)(iii). Further, Congress amended the MSP Act in 1986 to include "a private cause of action for damages (which shall be in an amount double the amount otherwise provided) in the case of a primary plan which fails to provide for primary payment (or appropriate reimbursement) in accordance" with the MSP Act. 42 U.S.C. § 1395y(b)(3)(A).

Congress later clarified in 2003 that "primary plans" under the Act may include putative tortfeasors. As "primary plans," such tortfeasors are potentially liable if they fail to reimburse Medicare for the costs it incurred in treating injured enrollees. *See* 42 U.S.C. § 1395y(b)(2)(B)(ii). Accordingly, Medicare can sue putative tortfeasors for double damages under 42 U.S.C. § 1395y(b)(3)(A).

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[2] "A primary plan, and an entity that receives payment from a primary plan, shall reimburse the appropriate [Medicare] Trust Fund for any payment made by the Secretary [of the Department of Health and Human Services ("HHS")] under this subchapter with respect to an item or service if it is demonstrated that such primary plan has or had a responsibility to make payment with respect to such an item or service." 42 U.S.C. § 1395y(b)(2)(B)(ii).

In 1997, Congress created the Medicare Advantage program under Part C of the Medicare Act. *See* 42 U.S.C. §§ 1395w-21 to 1395w-29. Under this program, Medicare enrollees may elect to receive their benefits from a private insurer, called a Medicare Advantage Organization ("MAO"), rather than from the government. MAOs enter into contracts with the Center for Medicare and Medicaid Services ("CMS"), the branch of the U.S. Department of Health and Human Services ("HSS") that administers the Medicare program. Under these contracts, CMS pays an MAO a fixed amount for each enrollee, and the MAO must provide at least the same benefits and services that the enrollee would receive under Medicare. *See* 42 U.S.C. § 1395w-22(a)(1)-(3).

Respondents Humana Medical Plan, Inc. and Humana Insurance Company (collectively, "Humana") are insurance companies that operate as MAOs. Pet. App. 52-53a. In November 2010, Humana filed a class action complaint against Petitioners in the U.S. District Court for the Eastern District of Pennsylvania. *Id.* Claiming that the MSP Act provides MAOs with a private cause of action for double recovery, Humana sought damages for Petitioners' failure to reimburse Humana for costs it incurred treating its enrollees for injuries allegedly related to Avandia, a Type 2 diabetes drug manufactured by GlaxoSmithKline. *Id.* at 57-62a. Arguing that no private cause of action exists for MAOs under the MSP Act, Petitioners moved to dismiss the action.

The district court dismissed Humana's complaint for failure to state a claim. Pet. App. 34-

51a. Analyzing the statute's text, structure, and purpose, the district court concluded that the private cause of action expressly given to Medicare in the MSP Act did not apply to MAO's, nor did the secondary payer provision of Medicare Advantage (in Part C of the Medicare Act) create such a private cause of action for MAOs. *Id.* at 45a. The district court also found no implied right of action for MAO's in the MSP Act under the four-part test established by this Court in *Cort v. Ash*, 422 U.S. 66 (1975). Finally, because the district court found that the MSP Act's silence on the existence of a private cause of action for MAO's did not create an ambiguity, it declined to defer to a CMS regulation purporting to grant MAO's a private cause of action on a par with that of Medicare. *See* Pet. App. 48-49a. The district court noted that MAOs were not without any remedy, as they still enjoyed the remedy of pursuing a "standard insurance contract claim brought in state court." *Id.* at. 41-47a

On appeal, the U.S. Court of Appeals for the Third Circuit reversed, holding that the MSP Act "provides Humana with a private cause of action against [Petitioners]." Pet. App. 3a. The appeals court concluded that the MSP Act's private cause of action was broad enough to include double-damages suits by MAOs because the statute "plac[es] no limitations upon which private (i.e., non-governmental) actors can bring suit for double damages when a primary plan fails to appropriately reimburse any secondary payer." *Id.* at 13a. In the panel's view, if Congress had wanted to exclude private insurers from the scope of the private cause of action, it should "have done so explicitly." *Id.* at 15a. Because "MAOs would be at a competitive

disadvantage" with Medicare without the ability to obtain double damages, the appeals court concluded that providing MAOs with a private cause of action was necessary "to facilitate recovery of conditional payments." *Id.* at 22-24a. In any event, the appeals court explained that even if the statute were ambiguous, according the necessary *Chevron* deference to the relevant CMS regulation would have required the same result. *Id.* at 27a.

REASONS FOR GRANTING THE PETITION

The Petition raises issues of exceptional importance. To ensure mandatory reimbursement for Medicare by a primary payer, the MSP Act provides that the United States may bring an action for reimbursement against all entities that were required to make payment for healthcare services under a "primary plan." *See* 42 U.S.C. § 1395y(b)(2)(B) (iii). To further facilitate that objective, Congress amended the MSP Act in 1986 to include "a private cause of action for damages (which shall be in an amount double the amount otherwise provided) in the case of a primary plan which fails to provide for primary payment (or appropriate reimbursement) in accordance" with the MSP Act. 42 U.S.C. § 1395y(b)(3)(A). The Third Circuit nonetheless held that, in addition to the United States, MAOs and other private parties may take advantage of the MSP Act's double-damages remedy to sue putative tortfeasors. Review is warranted to consider whether the appeals court's holding is consistent with this Court's precedents and with congressional intent.

The Petition exhaustively details the conflicting approaches of the federal appeals courts as to the scope of the private cause of action created by Congress in the MSP Act. Rather than repeat that analysis here, WLF writes separately to focus on the appeals court's erroneous interpretation of the MSP Act and its unwarranted deference to CMS.

This case hinges on whether Congress intended to allow MAOs and other private parties to invoke the MSP Act's double-damages remedy against putative tortfeasors. Contrary to the reasoning of the Third Circuit, *nothing* in the MSP Act grants the right to an MAO to recover payments that were not made by the Secretary of Health and Human Services out of the Medicare Trust Fund. And because Medicare did not make the payments that Humana now seeks to recover, no private cause of action is available under the MSP Act. Likewise, a comparison of the MSP Act's mandatory reimbursement provisions and the permissive MAO-related provisions of § 1395w-22(a)(4) in Part C further demonstrates that Congress did not intend to create a private cause of action in the latter statute. Other parts of the Medicare Act, including the Medicare prescription drug program under Part D, further show that Congress did not intend the remedy provided in the MSP Act to apply to MAOs.

Also misguided is the Third Circuit's conclusion that *Chevron*-type deference is owed to a 2005 amendment to the CMS's implementing regulations. While the statute unambiguously gives MAOs the right to charge primary payers, nowhere does it confer a private remedy on MAOs to enforce that right. Rather, MAOs are left to enforce their

rights as secondary payers under the common law of contracts. And so where, as here, Congress has spoken directly to the rights of the federal government versus the rights of MAOs, CMS's implementing regulations are irrelevant. Even if congressional intent was ambiguous, the CMS regulation is not a permissible construction of the statute, as the Secretary cannot invoke a right that Congress never created.

Finally, review is warranted not simply because the Third Circuit's holding conflicts sharply with long-accepted notions of statutory interpretation and agency deference, but also because that holding raises issues of the utmost importance to the nation's healthcare delivery system. The holding below, if left undisturbed, will have a major impact on a significant number of present and future litigants in the health care sector, and will result in an explosion of unintended private litigation under Medicare Part C.

I. REVIEW IS WARRANTED TO CORRECT THE THIRD CIRCUIT'S ERRONEOUS INTERPRETATION OF THE SCOPE OF THE MSP ACT'S PRIVATE CAUSE OF ACTION

The "central inquiry" in this case is "whether Congress intended to create, either expressly or by implication, a private cause of action" for MAOs under the MSP Act. *Touche Ross & Co. v. Redington*, 442 U.S. 560, 575 (1979). When it established a private cause of action for the federal government under the MSP Act, Congress was concerned with establishing the priority of payment

between Medicare and primary payers while providing the government with a special enforcement mechanism when the primary payer defaults, thus requiring the Medicare Trust Fund to make payment. That is why any party seeking to invoke the private cause of action in section 1395y(b)(3)(A) of the MSP Act must first establish that a primary plan failed to "reimburse the appropriate Trust Fund for any payment made *by the Secretary*." *See* 42 U.S.C. § 1395y(b)(2)(B)(2) (emphasis added).

Medicare pays an MAO a set amount for each enrollee according to a formula. The MAO then uses these funds to help cover health care services for its enrollees. *See* 42 U.S.C. § 1395w-23. Importantly, an MAO does not receive additional money from Medicare if an enrollee requires covered benefits in excess of the allotted Medicare amount, nor must an MAO return any unused funds to the Medicare Trust Fund. Thus, when an MAO like Humana seeks reimbursement under the MSP Act, it does so solely to recoup its own payments. Such reimbursement by a private insurer is obviously not intended to recover a payment "made by the Secretary." *See* 42 U.S.C. § 1395y(b)(2)(B)(2). Nor would such reimbursement be for the benefit of "the appropriate Trust Fund." *Id.* Here, Humana seeks reimbursement solely for payments that it made directly to its enrollees, not for payments made by the Secretary. Accordingly, the private cause of action in section 1395y(b)(3)(A) of the MSP Act simply does not apply.

The Third Circuit found otherwise, concluding that the MSP Act's private cause of action was broad enough to include double-damages suits by MAOs

because the statute "plac[es] no limitations upon which private (i.e., non-governmental) actors can bring suit for double damages when a primary plan fails to appropriately reimburse any secondary payer." Pet. App. 13a. But it is highly unlikely that Congress intended to hide "an elephant in a mousehole" in this fashion. That is, if Congress intended to create a private cause of action for private insurers to recoup double their own payments, it is highly unlikely that it would hide that intent in a statutory subsection entitled "Medicare as Secondary Payer." *See* 42 U.S.C. § 1395y(b)(2)(B)(2); s*ee also Whitman v. Am. Trucking Ass'ns, Inc.*, 531 U.S. 457, 468 (2001) ("Congress . . . does not . . . hide elephants in mouseholes."). It is even less likely that Congress would bury that intent in a statute that was enacted eleven years *before* the creation of the Medicare Advantage program.

It is true that Part C of the Medicare statute cross-references certain provisions of the MSP Act for reasons unrelated to establishing a private remedy, but cross-reference is by no means the same thing as incorporation. Indeed, when it enacted the Medicare Advantage program under Part C in 1997, Congress carefully considered the rights that an MAO should enjoy when it makes payments that would otherwise be the responsibility of a primary payer under the MSP Act. Congress could have explicitly incorporated the MSP Act into Part C, granted MAO's the same rights as the federal government, and placed payments by MAO's on the same footing as payments by Medicare. It did not.

Instead, Congress merely provided that, in those circumstances where payments by the government would be secondary under the MSP Act, MAO's have the option of *charging* the party that would otherwise be the primary payer. *See* 42 U.S.C. § 1395w-22(a)(4). But the right to "charge" is not the right to sue in court for double damages. Rather, Part C merely defines the circumstances under which an MAO may charge a primary payer, but never extends the rights of MAOs beyond the right to "charge" specified in Section 1395w-22(a)(4). As this Court has long recognized, "it is an elemental canon of statutory construction that where a statute expressly provides a particular remedy or remedies, a court must be chary of reading others into it." *Transamerica Mort. Advisors v. Lewis*, 444 U.S. 11, 19 (1979).

Likewise, a straightforward comparison of the the MSP Act's reimbursement provisions and the MAO-related provisions of § 1395w-22(a)(4) in Part C further demonstrates that Congress did not intend to create a private cause of action in the latter statute. Whereas the MAO provision uses permissive language (i.e., an MAO "may charge" to obtain reimbursement), the MSP Act uses mandatory language (i.e., all Medicare payments "shall" be conditioned on reimbursement by the primary insurer). This further confirms that Congress intended for Medicare to have greater rights, and more extensive remedies, than Medicare-substitute MAOs.

Other parts of the Medicare Act evince that Congress did not intend the remedy provided in the MSP Act to apply to MAOs. In 2003, Congress

passed the Medicare prescription drug program, which became Medicare Part D. *See* 42 U.S.C. §§ 1395w-101, *et seq*. To establish the rights of private insurers who provide drug benefits in cases where another entity is responsible for primary payment, Congress incorporated (rather than cross-referenced) another provision of the Medicare Act—but *not* the MSP Act. Instead, Congress incorporated the more limited set of remedies available to MAOs under Part C, in section 1395w-22(a)(4). Thus, Congress clearly intended to distinguish between the rights and remedies available when Medicare makes a secondary payment and when that payment is made by a private insurer, regardless whether that payment is made under Part C or Part D. After all, Congress knows how to incorporate an existing provision into a new statute when it wants to, and it plainly did not do so when enacting section 1395w-22(a)(4). If Congress had wanted the remedies of the MSP Act to apply to MAOs under Part C, it would have incorporated those provisions and not merely cross-referenced another provision of the MSP Act.

Where an express remedy is "by its terms limited" to a particular party, this Court has been "extremely reluctant to imply a cause of action . . . that is significantly broader than the remedy Congress chose to provide." *Touche Ross*, 442 U.S. at 572. And even if MAOs are intended beneficiaries of the MSP Act, it does not follow that Congress intended to confer a private cause of action on them. *Alexander v. Sandoval*, 532 U.S. 275, 286 (2001) (emphasizing that the statute must manifest an intent "to create not just a private right but also a private remedy"). Indeed, this Court has repeatedly

held that the mere fact that a plaintiff is an intended beneficiary of a federal statute is insufficient to justify a conclusion that Congress intended to bestow that plaintiff with a private right of action under that statute.

For example, the Court held that Congress did not intend to create a private right of action for those injured due to violations of the Investment Advisors Act of 1940, 15 U.S.C. § 80b-1, *et seq*., even though such individuals unquestionably were the very people Congress intended to protect when it adopted the Act. *See Transamerica Mort. Advisers*, 444 U.S. at 11. Similarly, the Court has held that Congress did not intend to create a private right of action under the Employee Retirement Income Security Act (ERISA) for a beneficiary of a disability income plan seeking to sue a plan fiduciary that breached its fiduciary duties to the beneficiary under ERISA, even though ERISA undoubtedly was adopted for the benefit of such beneficiaries. *See Mass. Mut. Life Ins. Co. v. Russell*, 473 U.S. 134 (1985).

II. REVIEW IS WARRANTED TO RESOLVE THE CONFLICT BETWEEN THE DECISION BELOW AND THIS COURT'S PRECEDENT ON AGENCY DEFERENCE

In determining whether MAOs enjoy a private cause of action under the MSP Act, the Third Circuit concluded that *Chevron*-type deference was owed to a 2005 amendment to the CMS's implementing regulations. That amendment provides that "the MA organization will exercise the same rights to recover from a primary plan, entity, or individual that the Secretary exercises under the MSP regulations in

subparts B through D of part 411 of this chapter." 42 C.F.R. § 422.108(f). But where, as here, Congress has spoken directly to the rights of the federal government versus the rights of MAOs, CMS's implementing regulations are irrelevant. *Chevron USA, Inc. v. Natural Res. Def. Council*, 467 U.S. 837, 843 (1984) ("If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress.").

The MSP Act is not silent as to an MAO's secondary payer rights. Indeed, MAOs enjoy their own secondary payer provision. *See* 42 U.S.C. § 1395w-22(a)(4). While that statute references and incorporates certain definitions from § 1395y(b), it neither expressly nor impliedly incorporates any other provision. And while § 1395w-22(a)(4) unambiguously gives MAOs the right to charge primary payers, nowhere does it confer a private remedy on MAOs to enforce that right. Rather, MAOs were left to enforce their rights as secondary payers under the common law of contracts.

As explained by CMS in its proposed rulemaking at the time, the 2005 amendment merely reflected Congress's "unambiguous" intent to "prohibit[] States from exercising authority over [MAO] plans in any area other than State licensing laws and State laws relating to plan solvency." 69 Fed. Reg. 46880 (Aug. 3, 2004).[3] As demonstrated

[3] Before amendment, the relevant portion of subsection (f) provided:

above, however, Congress did *not* amend the language of Section 1395w-22(a)(4) to create a cause of action or to otherwise confer on MAOs the rights conferred on the United States in section 1395y(b). Nor did Congress authorize CMS to unilaterally extend those rights to MAOs.

Of course, the aforementioned "regulations in subparts B through D of part 411" that are referenced in § 422.108(f) define and implement the rights of the Secretary of HHS (i.e., the United States) under § 1395b, including the right to recover double damages from primary payers. *See* 42 C.F.R. § 411.24. Thus, if § 422.108(f) grants MAOs the "same rights" as those enjoyed by the Secretary, it purports to impart rights to MAOs through mere regulation that were never granted by the MSP Act itself. This it cannot do.

Even if congressional intent was ambiguous, the CMS regulation is not a permissible construction of the statute, as the Secretary cannot invoke a right that Congress never created. This Court has consistently held that a regulation may not "conjure up a private cause of action that has not been authorized by Congress." *Alexander*, 532 U.S. at 291. Indeed, "language in a regulation may invoke a

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> A State cannot take away an [MAO's] rights under Federal law and the MSP regulations to bill, or to authorize providers and suppliers to bill, for services for which Medicare is not the primary payer. Section 1852(a)(4) of the Social Security Act does not prohibit a State from limiting the amount of th recovery; thus, State law could modify, but not negate, an [MAO's] rights in this regard."

65 Fed. Reg. 40320-21 (June 29, 2000).

private right of action that Congress through statutory text created, but it may not create a right that Congress has not." *Id.* Because CMS's interpretation of an MAO's rights under the MSP Act is wholly inconsistent with the statute itself, it is entitled to no deference. *Brown v. Gardner*, 513 U.S. 115, 122 (1994) (establishing that a regulation that "flies against the plain language of the statutory text exempts courts from any obligation to defer to it").

III. REVIEW IS WARRANTED BECAUSE OF THE IMPORTANCE OF THE QUESTION PRESENTED AND ITS RECURRING NATURE

Review is warranted not simply because the Third Circuit's holding conflicts sharply with long-accepted notions of statutory interpretation and agency deference, but also because that holding raises issues of the utmost importance to the nation's healthcare delivery system. The judicial creation of a private cause of action for private insurers to sue putative tortfeasors for double damages is no small matter. Indeed, the appeals court's novel interpretation of § 1395y(b)(3)(A) admittedly imposes "*no limitations* upon which private (i.e., non-governmental) actors can bring suit for double damages" against putative tortfeasors for double damages under the MSP Act. *See* Pet. App. 13a. As a result, the holding below will only encourage run-of-the-mill tort plaintiffs who receive benefits from Medicare (or MAOs) to bring suit in federal court seeking double damages under the MSP Act. This is a result Congress never could have intended.

Review is also warranted because the holding below will have a major impact on a significant number of present and future litigants in the health care sector. To be sure, the question presented by the Petition—whether MAOs and other private parties may invoke the MSP Act's double-damages remedy against putative tortfeasors—reaches well beyond the concerns of one pharmaceutical manufacturer in a single lawsuit. At present, there are over 400 different MAOs throughout the nation, offering more than 2,800 Medicare Advantage plans to some 13 million beneficiaries. Pet. App. 57a. If the decision below is left undisturbed, virtually every pharmaceutical, medical device, and health-care company will face MAO claims of the type at issue here. Although there will be substantial reason to question the validity of many of those suits, the difficulty and expense of defending against statutory claims of this nature will mean that defendants—if they cannot prevail on a motion to dismiss—will likely feel compelled to settle, sometimes for very substantial sums. Clarification of the scope of the MSP Act's cause of action is thus urgently needed, and only this Court can provide the necessary certainty to the affected industry. Nor is there any reason to delay review of the issue; the conflict among the federal appeals courts is pronounced and shows no signs of abating on its own.

CONCLUSION

For the foregoing reasons, the Petition for a Writ of Certiorari should be granted.

Respectfully submitted,

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