No. 11-269

In the Supreme Court of the United States

BLACKSTONE MEDICAL, INC.,

Petitioner,

v.

UNITED STATES OF AMERICA EX REL.
SUSAN HUTCHESON,

Respondent.

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

BRIEF OF AMGEN INC. AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

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INTEREST OF THE *AMICUS CURIAE*[1]

Amgen Inc. ("Amgen") is one of the world's largest biotechnology companies. The therapies Amgen has developed are used to treat patients suffering from cancer, kidney disease, rheumatoid arthritis, bone disease and other serious illnesses.

A large portion of Amgen's business in the United States depends on reimbursement under Medicare Part B. As a result, Amgen has a substantial interest in the intersection between the False Claims Act (the "FCA") and the complex regulatory scheme that governs claims for reimbursement under Medicare and Medicaid. In recent years, there has been an explosion in FCA litigation against manufacturers of drugs, biologics and medical devices for allegedly "causing" hospitals and other medical providers to submit "false or fraudulent" claims for Medicare or Medicaid reimbursement. Amgen is currently a defendant in one such lawsuit in the District of Massachusetts, which was unsealed in 2009. *United States ex rel. Westmoreland* v. *Amgen Inc.*, No. 06-10972-WGY (D. Mass).

Westmoreland and the instant case have been linked since 2010, when the district court dismissed *Westmoreland* based primarily on its analysis of the

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[1] Pursuant to Rule 37.6, Amgen affirms that no counsel for a party authored this brief in whole or in part and that no person other than Amgen and its counsel made a monetary contribution to its preparation or submission. Counsel of record for all parties received notice at least 10 days prior to the due date of the intention of *amicus* to file this brief. The parties' letters consenting to the filing of this brief have been filed with the Clerk's office.

concept of "legal falsity" in this case. *See Westmoreland*, 707 F. Supp. 2d 123, 133-34 (D. Mass. 2010), citing *United States ex rel. Hutcheson* v. *Blackstone Medical, Inc.*, 694 F. Supp. 2d 48 (D. Mass. 2010). The plaintiffs' appeals in *Hutcheson* and *Westmoreland* were argued on the same day, before the same panel in the First Circuit.[2] After the First Circuit reversed in *Hutcheson*, it applied the new test it had adopted in *Hutcheson* to reinstate most of the plaintiffs' claims in *Westmoreland* as well. *See State of New York* v. *Amgen Inc.*, __ F.3d __, 2011 WL 2937420 (1st Cir. July 22, 2011). Amgen and its co-defendants have filed their own petition for certiorari seeking review of that decision, which has been docketed as No. 11-363.

Amgen files this *amicus* brief out of a broad concern about the rapid expansion of FCA litigation. If allowed to stand, the First Circuit's decision in *Hutcheson* would inevitably accelerate that trend, by allowing *qui tam* plaintiffs who file in the First Circuit to use the FCA as a vehicle to seek massive damages

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[2] Relator alleged that Amgen had "caused" medical providers to submit "false or fraudulent" claims for reimbursement to both Medicare and Medicaid. She brought federal FCA claims on behalf of the United States arising out of the allegedly false Medicare claims and state FCA claims on behalf of a number of states arising out of the allegedly false Medicaid claims. Five intervening States and relator, on behalf of two other states, appealed from the dismissal of their Medicaid-related claims. Relator chose not to appeal the dismissal of her federal FCA claims, filing a fourth amended complaint instead. The district court concluded that that complaint stated a claim. *See United States ex rel. Westmoreland* v. *Amgen Inc.*, 738 F. Supp. 2d 267 (D. Mass. 2010).

and penalties for a wide variety of alleged regulatory, statutory or contractual defaults. That result would hurt not only Amgen, but everyone who does business with either the government or government providers.

SUMMARY OF ARGUMENT

As Blackstone's petition demonstrates, the Circuits have "splintered" on the proper approach to take regarding the concept of "legal falsity." Virtually all of the Circuits have now weighed in on that issue; collectively, they have come up with a dizzying array of different standards. These varying standards will be outcome determinative in many cases. *Hutcheson* itself proves the point, as does the First Circuit's decision applying *Hutcheson* to reverse the dismissal of the *Westmoreland* complaint. As demonstrated below, the dismissals in both cases would have been affirmed under the more stringent standards imposed in many, if not most, of the other Circuits.

The nature and extent of the Circuit split is enough, in and of itself, to warrant this Court's review. In addition, however, the sheer magnitude of FCA litigation and the burden that litigation imposes both on the government and on those who do business, directly or indirectly, with government entities makes it imperative that the Court resolve the issues raised by Blackstone's petition sooner rather than later.

ARGUMENT

I. THE CIRCUIT SPLIT BLACKSTONE IDENTIFIES IS DEEP, MATURE AND OUTCOME DETERMINATIVE.

Blackstone's petition outlines in detail the ways in which the Circuits have fractured on the issue of "legal falsity." Before *Hutcheson*, the Circuits had largely agreed on the basic theory behind the "legal falsity" concept — that a factually accurate claim can be rendered "false or fraudulent" within the meaning of the FCA if, in order to get paid, the claimant falsely certifies that he, she or it has complied with a legal obligation that is a prerequisite to payment. But the Circuits differed significantly on how the certification concept should be applied; those differences were particularly acute on the issue of whether and under what circumstances a certification of compliance could be inferred from the mere act of submitting a claim.[3]

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[3] For example, the Seventh Circuit has taken a position that is incompatible with the concept of implied certification. *See United States ex rel. Yannacopoulos* v. *General Dynamics*, __ F.3d __, 2011 WL 3084932, at *3 n.4. (7th Cir. July 26, 2011) ("[t]he FCA is a fraud prevention statute; violations of * * * regulations are not fraud unless the violator knowingly lies to the government about them"). In *Mikes* v. *Straus*, 274 F.3d 687, 700 (2d Cir. 2001), the Second Circuit adopted a narrow version of the implied certification theory, holding that "implied false certification is appropriately applied only when the underlying statute or regulation upon which the plaintiff relies *expressly* states the provider must comply in order to be paid." The D.C. Circuit, by contrast, applied the concept very broadly in *United States* v. *Science Applications Int'l Corp.*, 626 F.3d 1257, 1261 (D.C. Cir. 2010), holding that a claimant could be deemed to have impliedly certified compliance with any contractual obli-

In *Hutcheson*, the First Circuit deepened the existing Circuit split by dispensing with the concept of certification altogether. Under a certification theory, a claim cannot be considered false or fraudulent if the party submitting the claim *truthfully* certifies its own compliance with the legal obligations in question. That was the situation here, where hospitals submitted claims to Medicare for surgeries that were performed using Blackstone's medical devices and periodically certified their own compliance with the Anti-Kickback Statute (the "AKS"), 42 U.S.C. § 1320a-7b(b). Although the relator admitted that the hospitals had no knowledge that Blackstone was allegedly offering kickbacks to prescribing physicians, the First Circuit concluded that the hospitals' claims could nevertheless be deemed "false or fraudulent" under the FCA. The court of appeals reached that conclusion by treating the hospitals' certifications and Medicare enrollment agreements as (i) evidence that compliance with the AKS was a "material precondition of payment" of Medicare claims and (ii) a representation that there had in fact been compliance with the AKS at every step in the supply chain. Pet. App. 34a.

As Blackstone demonstrates in its petition (at 29-30), the outcome in this case would have been very different had the case been heard in a variety of other Circuits. The same is true of the First Circuit's subsequent decision in *Westmoreland*, in which the court of appeals applied its reasoning in *Hutcheson*

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gation so long as a court subsequently determined that it was "material" to the government's decision to pay the claim.

to reverse the dismissal of claims brought under a variety of state false claims acts.[4]

In *Westmoreland*, the plaintiffs alleged that Amgen and its co-defendants had marketed an Amgen product (Aranesp®) in a way that supposedly violated anti-kickback statutes and, in so doing, had caused Medicaid providers to submit "false or fraudulent" claims every time they sought reimbursement from Medicaid for Aranesp®. The district court dismissed that claim because it concluded that Medicaid providers had never certified their compliance with anti-kickback statutes, either expressly or impliedly. *Westmoreland*, 707 F. Supp. 2d at 136, 138. That conclusion was clearly right under the standards applied in other Circuits. Medicaid providers were never required to explicitly certify that they had complied with the AKS or analogous state anti-kickback statutes. Furthermore, there were no statutes or regulations that told providers that Medicaid claims would not be paid if the provider or a party somewhere in the supply chain had violated anti-kickback laws. *Id.*

Nevertheless, the First Circuit reversed the dismissal of virtually all of plaintiffs' claims, on the theory that it was irrelevant to the falsity analysis whether the providers had in fact certified their compliance. The First Circuit held that the critical issue was whether compliance with anti-kickback

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[4] The court of appeals held that "our decision in *Hutcheson*, 647 F.3d 377, controls" because, among other things, of the "substantive similarity of the state FCAs invoked here and the federal FCA with respect to the provisions at issue in this litigation." 2011 WL 2937420 at *5.

laws was a "material precondition of payment." The court of appeals then defined that concept extremely broadly, holding that compliance constituted a "material precondition of payment" so long as the rules and regulations arguably gave the government agency the *discretion* to deny payment or to terminate the provider's participation in the Medicaid program as a result of the anti-kickback violations. *See* 2011 WL 2937420 at *7-8. Having concluded that compliance with anti-kickback laws was a "precondition of being entitled to payment," the court held that merely by submitting Medicaid claims the providers had "represented" that there had been compliance with anti-kickback laws — a representation that was rendered "incorrect" by the alleged kickbacks. *Id.* at *8-9.

As it had in *Hutcheson*, the court of appeals held that it was "of no moment" that the regulations and provider agreements it cited addressed the *providers'* compliance with anti-kickback laws. *Id.* at *9.[5] The court concluded that it was enough that the *defendants* were alleged to have knowingly violated anti-kickback laws, thereby "causing" the providers to submit claims that made their supposed "representations" that there had been compliance throughout the supply chain "incorrect." *Id.*

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[5] Amgen argued that one of plaintiffs' kickback theories was so novel and attenuated that providers would not have understood that they had received a kickback. Thus, like the hospitals here, those providers did not make any statement that was false even if they could be deemed to have certified their own compliance with anti-kickback laws. The court brushed off this argument in a footnote, on the grounds that the providers' state of mind was irrelevant and that, in any event, plaintiffs had sufficiently alleged that they acted with scienter. *Id.* at *9 n.12.

Westmoreland illustrates just how far the First Circuit has strayed from the "certification" construct that prevails in most of the other Circuits. Under the approach taken by the Second Circuit and a number of other Circuits as well, the submission of a claim can be deemed an implied certification of compliance only where a statute or regulation makes it clear that the claim *will not* be paid absent compliance. *See, e.g.*, *Mikes* v. *Straus*, 274 F.3d at 700; *United States ex rel. Wilkins* v. *United Health Group, Inc.*, __ F.3d __, 2011 WL 2573380, at *9 (3d Cir. June 30, 2011); *United States ex rel. Vigil* v. *Nelnet, Inc.*, 639 F.3d 791, 795–96 (8th Cir. 2011). In each of these cases, the courts have distinguished between conditions of payment and conditions of continued participation in the program, holding that a claim cannot be deemed false simply because the claimant has engaged in conduct that could (but need not) result in expulsion from the program or other disciplinary sanctions.

In *Hutcheson* and again in *Westmoreland*, the First Circuit brushed off the distinction between conditions of payment and conditions of participation. The court departed from the rule applied in other Circuits by adopting a much broader definition of a "condition of payment," focusing on whether there is any possibility that the claim *could have* been denied if the truth had been known, as opposed to whether a statute or regulation *required* it to be denied. And it staked out the most extreme position of any Circuit by holding that the mere submission of a claim constitutes a "representation" that there has been compliance not only by the claimant itself, but also by third parties in the supply chain.

The fact that it is irrelevant under the First Circuit's analysis whether the party submitting the claim knew that there had been an AKS violation demonstrates just how extreme the First Circuit's position is and how disconnected it has become from the theory behind the "implied certification" concept employed in other Circuits. The theory is that the act of submitting a claim constitutes a representation that the claimant has complied with all conditions it must meet in order to get paid. But if the provider does not know that there has been a violation of the AKS or any other condition of payment, any such implied certification would be true and thus cannot provide a logical basis for labeling the claim "false or fraudulent."

Similarly, the notion that compliance is in fact a precondition of payment falls apart if the provider is innocent. Even if the First Circuit was right that administrators *could have* denied providers' claims because *someone else* violated the AKS, it seems highly unlikely that they would have punished an innocent provider by refusing payment. Under these circumstances, the notion that compliance with anti-kickback laws is in fact a "material precondition of payment" is merely a convenient legal fiction used to create "falsity" where none exists.

The bewildering array of approaches the various Circuits have taken over the course of the last decade to the issue of "legal falsity" under the FCA demonstrates the need for this Court's review of the questions presented by Blackstone's petition. Further litigation of these issues in the lower courts is not likely to resolve the conflict; on the contrary, the most recent cases suggest that further litigation will simp-

ly generate more confusion and result in more disparate outcomes.

II. REVIEW IS WARRANTED IN LIGHT OF THE BURDEN IMPOSED BY FCA LITIGATION.

FCA litigation has become a big business in recent years. As Blackstone points out, thousands of FCA cases have been filed over the course of the last decade.[6] The District of Massachusetts, in particular, has become a focal point for FCA claims against manufacturers of pharmaceuticals, biologics and medical devices. Indeed, there is such a backlog of FCA cases filed under seal in Massachusetts that some judges in that district have begun unsealing cases before the U.S. Attorney's Office has been able to finish its investigation and to decide whether or not to intervene.[7]

Many of the FCA claims filed over the last decade have been predicated on a "legal falsity" theory. The array of rules and regulations that apply to manufacturers of pharmaceuticals, biologics and medical devices and to Medicare and Medicaid

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[6] As of January 4, 2011, there were 1341 *qui tam* cases that were pending under seal in the federal courts, 885 alleging health care fraud and 180 alleging fraud in connection with pharmaceutical marketing. *See* Letter from Ronald Weich, Assistant Attorney Gen., U.S. Dep't of Justice, and Jim Esquea, Assistant Sec'y, U.S. Dep't of Health and Human Servs., to Sen. Charles E. Grassley 13 (Jan. 24, 2011).

[7] *See* Sheri Qualters, *Cases Deluge Boston Court: Judges Unseal Dormant False Claims Act Suits*, Nat'l L.J. (Aug. 1, 2011), noting that "[i]n recent years, whistleblowers have flooded Boston's federal court with health-care related False Claims Act cases."

claims have provided fertile grounds for *qui tam* plaintiffs pursuing novel theories of falsity. *Westmoreland* provides a good example. Plaintiffs' primary claim in that case is that Amgen violated anti-kickback laws by including allegedly excessive amounts of "overfill" in vials of Aranesp®. Under FDA regulations, all liquid injectable medicines like Aranesp® must contain more than the labeled amount to ensure that there is enough medicine to enable any provider or self-administering patient to withdraw the full amount of the labeled dose. *See* 21 U.S.C. § 351(b); 21 U.S.C. § 352; 21 C.F.R. § 201.51(g). In *Westmoreland*, plaintiffs alleged that Amgen had included more of this "overfill" in vials of Aranesp® than was necessary and used the excess as a marketing tool. During the period at issue, Medicare and Medicaid reimbursed providers for liquid drugs based on each unit of medicine they administered, rather than based on the cost of the individual vial. Plaintiffs alleged that Amgen's sales force had explained to some providers that they could profit by using the "overfill" in Aranesp® vials and then billing Medicare and Medicaid for it.

Plaintiffs argued that it was improper for providers to bill overfill under Medicare and Medicaid regulations.[8] But plaintiffs did not base their FCA claims on the theory that defendants had "caused" some

[8] Defendants disagreed. It was not until after the *Westmoreland* case was unsealed that the Centers for Medicare & Medicaid Services ("CMS") promulgated a new Medicare rule, which went into effect on January 1, 2011, prohibiting providers from billing for any overfill they administered. *See* Medicare Program: Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2011, 75 Fed. Reg. 40040 (July 13, 2010).

providers to improperly seek reimbursement for overfill. Instead, they sought to exponentially increase the potential recovery by converting a dispute over billing rules into a kickback scheme. Plaintiffs alleged that Amgen had included a "liquid kickback" in every vial of Aranesp® and that this alleged "kickback" tainted *every* claim for reimbursement that *every* provider submitted, regardless of whether the provider ever billed any overfill.

Claims that a manufacturer's marketing methods violated anti-kickback laws, which therefore resulted in the filing of false claims, are legion. *Qui tam* plaintiffs have also sought to use the FCA as an enforcement mechanism for other statutes and regulations as well. For example, there have been many FCA lawsuits unsealed in the last few years alleging that a manufacturer engaged in unlawful promotion of off-label use of its medical devices, which supposedly resulted in the submission of "false or fraudulent" claims by providers who chose to use those devices. *See, e.g.*, *United States ex rel. Nowak* v. *Medtronic, Inc.*, 2011 WL 3208007, at *29 (D. Mass. July 27, 2011).

Outside the Medicare/Medicaid context, FCA claims have been brought challenging a wide variety of different alleged failures to comply with regulatory or contractual obligations. For example, in *United States ex rel. Vigil* v. *Nelnet, Inc.*, 639 F.3d at 795, the relator sought to declare billions of dollars worth of claims false or fraudulent because of alleged violations of loan marketing regulations with respect to some loans. In *Schindler Elevator Corp.* v. *United States ex rel. Kirk*, 131 S. Ct. 1885 (2011), the relator alleged that $100 million worth of claims for elevator repair work were "false or fraudulent" because the

claimant had allegedly failed to file accurate annual reports regarding the number of Vietnam veterans it employed. And in *United States ex rel. Hendow* v. *Univ. of Phoenix*, 461 F.3d 1166 (9th Cir. 2006), the relator alleged that violations of rules regarding compensation of student recruiters rendered hundreds of millions' of dollars worth of student financial aid claims "false or fraudulent."

The burden on both businesses and government from this flood of litigation is substantial. FCA cases are generally complex, expensive and time-consuming to investigate and litigate. *Qui tam* plaintiffs typically invoke the FCA's draconian damages and penalty provisions to seek huge damages.[9] And even if the United States or the relevant states decline to intervene, as they do more often than not, *qui tam* plaintiffs can keep litigating FCA suits for years, inflicting enormous costs on defendants and putting them under intense pressure to settle regardless of the merits of the claim.

Under these circumstances, the threat of over-deterrence is very real: as the Eighth Circuit noted in *Vigil*, in many cases where the relator alleges violations of regulatory requirements, those claimed

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[9] Where there are a large number of relatively small claims, relators routinely urge courts to impose per claim penalties that multiply to astronomical sums. In one recent case in which the jury found actual damages of $4.6 million, the Commonwealth of Massachusetts requested over $191 million in civil penalties, arguing that defendants could have been held liable "for between $4,945,515,000 and $9,891,030,000 in civil penalties" because the jury found that nearly one million false claims had been presented. Mem. in Supp. of Mot. for Entry of J. at 1, 16, *Massachusetts* v. *Schering-Plough Corp.*, Civ. A. No. 03-11865-PBS (D. Mass. Dec. 10, 2010) (Docket No. 947).

violations should be handled through administrative enforcement mechanisms that were specifically designed to deal with them. 639 F.3d at 799. Enforcement through FCA litigation, by contrast, is likely to be extremely slow, expensive and ultimately ineffective as a way of regulating on-going conduct.

In *Astra USA, Inc.* v. *Santa Clara County*, 131 S. Ct. 1342, 1348 n.4 (2011), this Court refused to allow a third party to "'circumvent Congress's decision not to permit private enforcement'" of Section 340B of the Public Services Act by suing as a third-party beneficiary of pricing agreements that drug manufacturers had entered into with the Department of Health and Human Services to implement Section 340B. The Court explained that Congress had given HHS the sole responsibility of administering the Section 340B program; allowing private parties to sue could "spawn a multitude of dispersed and uncoordinated lawsuits by 340B entities" that would "undermine the agency's efforts to administer both Medicaid and § 340B harmoniously and on a uniform, nationwide basis." *Id.* at 1349. The same analysis applies here: giving private parties the power to use the FCA to enforce obligations purportedly imposed on government contractors by their contracts, statutes or regulations would inevitably undermine the government's ability to administer its own programs and contracts in a consistent and efficient manner.

Given the high-stakes nature of FCA litigation, it is particularly important to have clear guidelines as to what does (and does not) constitute a "false or fraudulent" claim. Under the current state of the law, there is massive confusion in the lower courts as to whether and under what circumstances a violation of an underlying legal obligation will be deemed to

render a claim "false or fraudulent." The Court should grant review in this case to remedy that confusion and to make clear that the FCA cannot be used as an all-purpose enforcement mechanism for any and all regulatory, statutory or contractual defaults.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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