

# United States Court of Appeals For the First Circuit

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Nos. 10-1629; 10-1630; 10-1633; 10-1634; 10-1635; 10-1636; 10-1954;  
10-1955

STATE OF NEW YORK; COMMONWEALTH OF MASSACHUSETTS; STATE OF  
CALIFORNIA; STATE OF ILLINOIS; STATE OF INDIANA; STATE OF NEW  
MEXICO EX REL. KASSIE WESTMORELAND; STATE OF GEORGIA EX REL.  
KASSIE WESTMORELAND,

Plaintiffs, Appellants,

UNITED STATES EX REL. KASSIE WESTMORELAND; STATE OF DELAWARE;  
STATE OF FLORIDA; STATE OF HAWAII; STATE OF LOUISIANA; STATE OF  
MICHIGAN; STATE OF NEVADA; STATE OF NEW HAMPSHIRE; STATE OF  
TENNESSEE; STATE OF TEXAS; COMMONWEALTH OF VIRGINIA; DISTRICT OF  
COLUMBIA,

Plaintiffs,

v.

AMGEN INC.; ASD HEALTHCARE; INTERNATIONAL NEPHROLOGY NETWORK,  
renamed INTEGRATED NEPHROLOGY NETWORK, d/b/a Dialysis Purchasing  
Alliance, Inc.,

Defendants, Appellees,

AMERISOURCEBERGEN SPECIALTY GROUP; AMERISOURCEBERGEN CORPORATION;  
IMMUNEX CORPORATION; MEDSCAPE, LLC; WEBMD HEALTH CORP.; WYETH;  
WYETH PHARMACEUTICALS,

Defendants.

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APPEALS FROM THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS  
[Hon. William G. Young, U.S. District Judge]

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Before

Lynch, Chief Judge,  
Lipez and Howard, Circuit Judges.

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Steven C. Wu, Assistant Solicitor General, with whom Eric T. Schneiderman, Attorney General, Barbara D. Underwood, Solicitor General, Richard Dearing, Deputy Solicitor General, Carolyn T. Ellis, Special Assistant Attorney General, Medicaid Fraud Control Unit, Margot Schoenborn, Special Assistant Attorney General, Medicaid Fraud Control Unit, of New York; Eliseo Z. Sisneros, Deputy Attorney General, Kamala D. Harris, Attorney General, Nicholas P. Paul, Deputy Attorney General, of California; Joseph B. Chervin, Assistant Attorney General, Lisa Madigan, Attorney General, of Illinois; Jessica L. Harlan, Deputy Attorney General, Medicaid Fraud Control Unit, Greg Zoeller, Attorney General, of Indiana; Ann B. Ackil, Assistant Attorney General, Medicaid Fraud Division, and Martha Coakley, Attorney General, of Massachusetts; were on brief, for State of New York, Commonwealth of Massachusetts, State of California, State of Illinois, and State of Indiana, appellants.

Derek T. Ho, with whom Silvija A. Strikis, Joseph S. Hall, Andrew S. Oldham, Kelloqq, Huber, Hansen, Todd, Evans & Figel, PLLC, Suzanne E. Durrell, Robert M. Thomas, Jr., and Royston H. Delaney were on brief, for Kassie Westmoreland, appellant.

Charles W. Scarborough, Appellate Staff, Civil Division, Department of Justice, with whom Tony West, Assistant Attorney General, Carmen Ortiz, United States Attorney, and Douglas N. Letter, Appellate Staff, Civil Division, Department of Justice, were on brief, for the United States, amicus curiae.

Michele Odorizzi, with whom Kenneth S. Geller, Andrew Tauber, Mayer Brown LLP, Brien T. O'Connor, Kirsten V. Mayer, William Dunn, Ropes & Gray LLP, Daniel A. Curto, Michael D. Kendall, and McDermott Will & Emery LLP were on brief, for Amgen Inc., appellee.

James M. Becker, with whom Buchanan Ingersoll Rooney PC, Eric W. Sitarchuk, Morgan Lewis & Bockius, LLP, Peter Ball, Ryan M. Cunningham, and Sally & Fitch were on brief, for International Nephrology Network and ASD Healthcare, appellees.

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July 22, 2011

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**LYNCH, Chief Judge.** Relator Kassie Westmoreland and the plaintiff state intervenors in this qui tam action appeal from a Rule 12(b)(6) dismissal of their pendent state False Claims Act (FCA) causes of action against Amgen, Inc. (Amgen), International Nephrology Network (INN), and ASD Healthcare (ASD). The district court exercised jurisdiction over the action, which also alleged violations of the federal FCA, 31 U.S.C. § 3729 et seq., pursuant to 31 U.S.C. § 3732(b), 28 U.S.C. § 1331, and 28 U.S.C. § 1367. We have jurisdiction over this appeal concerning only questions of state law pursuant to 28 U.S.C. § 1291.

This appeal raises a set of questions similar to those that arose recently for this circuit in United States ex rel. Hutcheson v. Blackstone Medical, Inc., No. 10-1505, 2011 WL 2150191 (1st Cir. June 1, 2011). Like the plaintiffs in Hutcheson, the plaintiffs in this appeal allege that the defendants caused the submission of false or fraudulent claims for government payment. Also like the plaintiffs in Hutcheson, they allege that the claims were false or fraudulent because the claims misrepresented that healthcare professionals had not received certain kickbacks. The plaintiffs in Hutcheson alleged that the defendants in that suit caused the submission of false or fraudulent claims to the federal Medicare agency in violation of the federal FCA. By contrast, the plaintiffs here on appeal allege that the defendants caused the

submission of false or fraudulent claims to state Medicaid agencies in violation of state FCAs.

Westmoreland and the state intervenors allege that Amgen, acting in concert with INN and ASD, employed an elaborate kickback scheme to induce medical providers to prescribe Aranesp, a drug Amgen manufactures to treat anemia. This kickback scheme, plaintiffs allege, contained two prongs. First, they allege that Amgen included extra Aranesp in its single-dose vials of the drug and encouraged providers to bill this free product to Medicaid. Second, they allege that Amgen, INN, and ASD channeled improper benefits to providers through sham consulting agreements, honoraria, retreats, and the like to encourage them to purchase Aranesp. Westmoreland and the state intervenors argue that these kickbacks rendered the reimbursement claims at issue in this litigation ineligible for payment, and that for this reason they have stated a claim under the seven relevant state FCAs.

The district court held that the plaintiffs could not survive a 12(b)(6) motion to dismiss because they had failed to identify a false or fraudulent claim for Medicaid payment within the meaning of those state FCAs. United States ex rel. Westmoreland v. Amgen, Inc., 707 F. Supp. 2d 123 (D. Mass. 2010). In so holding, the district court employed the same legal framework to analyze state FCA claims as it did to analyze federal FCA claims in United States ex rel. Hutcheson v. Blackstone Medical, Inc., 694

F. Supp. 2d 48 (D. Mass. 2010). We reject that framework, invoked on appeal by the defendants, to the extent that it is inconsistent with our decision in Hutcheson, 2011 WL 2150191, concerning what constitutes a false or fraudulent claim for government payment. The state FCA provisions at issue here are not relevantly different from the federal FCA provisions at issue in Hutcheson.

On the merits, we affirm in part and reverse in part. We reverse the district court's dismissal of the plaintiffs' claims under six of the seven state FCAs at issue and affirm on different grounds the district court's dismissal of the plaintiffs' claims under the remaining state FCA. The plaintiffs have more than adequately alleged that providers submitted claims that misrepresented compliance with a precondition of Medicaid payment in New York, Massachusetts, California, Illinois, Indiana, and New Mexico. With respect to the claims under Georgia's FCA, we affirm on different grounds the district court's holding that the plaintiffs have not identified a false or fraudulent claim for payment. The plaintiffs have not adequately alleged that the providers submitted claims to Georgia's Medicaid program that did not comply with a precondition of payment.

I.

Westmoreland initially brought this qui tam action against Amgen, INN, ASD, and two other corporate defendants under the federal FCA and various state FCAs on behalf of the United

States, seventeen individual states, and the District of Columbia. Westmoreland worked as an Amgen employee from September 2002 to mid-March 2005 and filed her first complaint on June 5, 2006.<sup>1</sup> The United States notified the district court on September 1, 2009 that it was not intervening in the action at that time. Fifteen states and the District of Columbia filed a multi-state complaint in intervention on October 30, 2009.

Westmoreland appeals the district court's dismissal of the state law claims she asserted on behalf of the two non-intervening states, Georgia and New Mexico, but she does not appeal the federal claims she asserted on behalf of the United States.<sup>2</sup> California, Illinois, Indiana, Massachusetts, and New York have also appealed the district court's dismissal of their claims.<sup>3</sup> On

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<sup>1</sup> In her first complaint, Westmoreland brought claims on behalf of only sixteen individual states. She later included claims on behalf of the state of Georgia in her first amended complaint, filed on July 2, 2007. The defendants have not challenged that amendment.

<sup>2</sup> The district court dismissed some of Westmoreland's federal claims under the first-to-file bar of the federal FCA and dismissed the remainder of her federal claims under Rule 12(b)(6). United States ex rel. Westmoreland v. Amgen, Inc., 707 F. Supp. 2d 123, 140 (D. Mass. 2010). The district court noted, however, that there appeared to be "a few allegations, albeit not fully developed and likely insufficient at this time, that may support alternative theories of liability" under the state and federal FCAs. Id. at 139. Westmoreland amended her complaint with respect to her claims under the federal FCA and has since survived a motion to dismiss those claims. See United States ex rel. Westmoreland v. Amgen, Inc., 738 F. Supp. 2d 267 (D. Mass. 2010).

<sup>3</sup> Among the fifteen state intervenors, six voluntarily dismissed their claims during the course of the district court's

appeal, the United States has been allowed to participate as an amicus in support of Westmoreland and the state intervenors. Amgen, INN, and ASD are the only remaining defendants on appeal.<sup>4</sup>

The factual allegations relevant to the claims on appeal are as follows. In 2001, the Food and Drug Administration (FDA) approved Amgen's drug Aranesp for treatment of anemia associated with chronic renal failure. A year later, the FDA approved Aranesp for the treatment of certain chemotherapy-induced anemia as well. Aranesp competes in these markets with Procrit, a drug also manufactured by Amgen but sold and marketed by a different company, Johnson & Johnson. Westmoreland and the state intervenors allege that Amgen, with the help of its co-defendants, employed a two-pronged kickback scheme to encourage providers to prescribe Aranesp rather than Procrit. Between 2001 and 2007, Amgen's revenue from Aranesp rose from \$27 million in 2001 to \$2.154 billion in 2007, and amounted to \$11 billion in the aggregate between 2001 and 2008.

Some kickbacks, plaintiffs allege, took the form of excess product included in Aranesp vials. Aranesp is an injectable drug sold in single-dose vials such that each vial is used for one patient in one administration of the drug. The United States

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proceedings. The District of Columbia and four states did not appeal the district court's decision.

<sup>4</sup> The two other corporate defendants initially named in this suit, AmerisourceBergen Specialty Group and AmerisourceBergen Corporation, were dismissed from this action by the district court. That ruling has not been appealed.

Pharmacopeia (USP) requires that a vial of injectable drug contain an amount of the drug in slight excess of the labeled volume to permit withdrawal and administration of the labeled amount. USP recommends that this "overfill" amount be up to 10% of the dosage. It is undisputed that Aranesp vials contained 19% overfill when the drug entered the marketplace in 2001, and 16.8% overfill between 2002 and 2008. It is also undisputed that medical providers generally may receive reimbursement from state Medicaid programs for administered overfill.

Westmoreland and the state intervenors allege that Amgen actively encouraged providers to bill excess overfill. Amgen's sales force, the plaintiffs allege, distributed economic analyses to medical providers that included assessments of how billing Aranesp overfill would impact and increase the providers' potential profits. The plaintiffs also allege that Amgen sales representatives promoted Aranesp by emphasizing the profit benefits of seeking reimbursement for overfill. Consonant with these alleged efforts, Amgen adjusted overfill amounts in Procrit such that the overfill amounts in Aranesp vials were 50% greater than the amounts in Procrit vials. The plaintiffs allege that Amgen knowingly created this disparity to give Aranesp a competitive advantage over Procrit.

Other kickbacks, plaintiffs allege, took the form of free weekend retreats, lavish advisory board meetings, sham honoraria,



consulting fees, and other benefits offered to induce medical providers to prescribe Aranesp rather than Procrit. The plaintiffs allege Amgen conveyed these benefits with the assistance of INN and ASD. INN is an entity that purported to operate as a group purchasing organization that purchased drugs in volume for the benefit of its members. ASD is a wholesale drug distributor and sister company of INN from which INN purchased Aranesp.

INN, the plaintiffs allege, received funds from Amgen disguised as administrative fees and used these funds to confer benefits to providers at Amgen's direction. ASD, they allege, participated in events INN put on to advance Aranesp, and provided Aranesp at lower prices to providers in return for payments funneled through INN. The plaintiffs allege that ASD price-fixing and discounting also increased profits for providers, as the Medicaid reimbursement amount would not be similarly reduced.

Westmoreland and the state intervenors argue that by paying these kickbacks, the defendants knowingly caused the providers to submit false or fraudulent claims for Medicaid payment in violation of the state FCAs in California, Georgia, Illinois, Indiana, Massachusetts, New Mexico, and New York. See California False Claims Act, Cal. Gov't Code §§ 12650 - 12656; Georgia State False Medicaid Claims Act, Ga. Code Ann. §§ 49-4-168 - 49-4-168.6;

Illinois Whistleblower Reward and Protection Act,<sup>5</sup> 740 Ill. Comp. Stat. §§ 175/1 - 175/8; Indiana False Claims and Whistleblower Protection Act, Ind. Code §§ 5-11-5.5-1 - 5-11-5.5-18; Massachusetts False Claims Act, Mass. Gen. Laws ch. 12, §§ 5A - 50; New Mexico Medicaid False Claims Act, N.M. Stat. Ann. §§ 27-14-1 - 27-14-15; New York False Claims Act, N.Y. State Fin. Law §§ 187 - 194.

Like the federal FCA, these state statutes impose liability on any person who (1) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval to a state, (2) knowingly makes, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state, or (3) conspires to defraud the state by getting a false claim allowed or paid. See Cal. Gov't Code §§ 12651(a)(1)-(3); Ga. Code Ann. §§ 49-4-168.1(a)(1)-(3); 740 Ill. Comp. Stat. §§ 175/3(a)(1)(A)-(C); Ind. Code § 5-11-5.5-2(b); Mass. Gen. Laws ch. 12, §§ 5B(1)-(3); N.M. Stat. Ann. §§ 127-14-4(A)-(D); N.Y. State Fin. Law §§ 189(1)(a)-(c). Six of the seven statutes provide that a defendant acts "knowingly" if he has "actual knowledge" of a claim or statement's truth or falsity, or "acts in deliberate ignorance" or "reckless disregard" to its truth or

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<sup>5</sup> In July 2010, during this litigation, an amendment re-titled this statute the Illinois False Claims Act. See 2010 Ill. Legis. Serv. 96-1304. The amendment made other changes to the act as well, but none of those changes are relevant here.

falsity. Cal. Gov't Code § 12650(b)(2); Ga. Code Ann. § 49-4-168(2); 740 Ill. Comp. Stat. § 175/3(b)(1); Ind. Code § 5-11-5.5-1(4); Mass. Gen. Laws ch. 12, § 5A(a); N.Y. State Fin. Law § 188(3). The New Mexico FCA does not itself define this term. See N.M. Stat. Ann. § 27-14-3.

Westmoreland and the state intervenors assert that a claim is false or fraudulent under these statutes if it misrepresents compliance with a precondition of payment. A medical provider that submits a claim for Medicaid reimbursement, they argue, impliedly represents that the claim is payable. The plaintiffs assert that the kickbacks provided by Amgen, INN, and ASD rendered Medicaid reimbursement claims submitted by medical providers for Aranesp ineligible for payment under the terms of state laws, regulations, and other documentation accompanying claims for payment submitted to state Medicaid programs. Because Amgen, INN, and ASD knowingly caused the submission of these claims, the plaintiffs allege, they violated the state FCAs.

The district court held that Westmoreland and the state intervenors had failed to state a claim under any of the state FCAs. Drawing on its analysis in Hutcheson, 694 F. Supp. 2d 48, the district court held that a claim can only be false or fraudulent if it is "factually false" or "legally false." A claim is factually false, it held, if it misstates facts. A claim can be legally false, it held, under either an "express certification

theory" or an "implied certification theory." Under the express certification theory, a claim is false or fraudulent if the submitting party expressly certifies compliance with a statute or regulation that is a precondition of payment but the party is not actually in compliance with that statute or regulation. Under the implied certification theory, a claim is false or fraudulent if the submitting party, without making any express certifications, has failed to comply with a precondition of payment expressly stated in a statute or regulation. Amgen, 707 F. Supp. 2d at 133.

Applying this framework, the district court held that Westmoreland and the state intervenors had failed to identify a false or fraudulent claim cognizable under the state FCAs. The plaintiffs, it held, had not argued that the claims were factually false, id. at 133, and had not shown that they were false or fraudulent under either the express or implied certification theories, id. at 139. As to the express theory, the district court held that statements in Medicaid provider agreements conditioning payment on compliance with applicable state and federal laws were too broad to establish an express certification of compliance with anti-kickback statutes. Id. at 136-37. As to the implied theory, the district court held that the plaintiffs had failed to identify a state law or regulation that expressly conditioned Medicaid reimbursement on compliance with anti-kickback statutes. Id. at 138-39. We rejected portions of this framework for analyzing

whether a claim is false or fraudulent in Hutcheson and we do so again here.

## II.

This court reviews de novo the grant of a motion to dismiss under Rule 12(b)(6), "accepting as true all well-pleaded facts, analyzing those facts in the light most hospitable to the plaintiff's theory, and drawing all reasonable inferences for the plaintiff." Hutcheson, 2011 WL 2150191, at \*5. To survive a motion to dismiss, a complaint must set forth "factual allegations, either direct or inferential, respecting each material element necessary to sustain recovery under some actionable legal theory." Id. (quoting Gagliardi v. Sullivan, 513 F.3d 301, 305 (1st Cir. 2008)) (internal quotation marks omitted).

Given the substantive similarity of the state FCAs invoked here and the federal FCA with respect to the provisions at issue in this litigation, the state statutes may be construed consistently with the federal act.<sup>6</sup> See Massachusetts v. Mylan Labs., 608 F. Supp. 2d 127, 140 (D. Mass. 2008) (citing Scannell v. Att'y Gen., 872 N.E.2d 1136, 1138 n.4 (Mass. 2007)); Kuhn v. LaPorte Cnty. Comprehensive Mental Health Council, No. 3:06-CV-317 CAN, 2008 WL 4099883, at \*3 n.1 (N.D. Ind. Sept. 4, 2008); Am.

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<sup>6</sup> To be clear, this federal case law dictates only a mode of analysis. It does not dictate that claims that are false or fraudulent under the federal FCA would necessarily be false or fraudulent under the state FCAs had they been submitted to a state government rather than the federal government, or vice versa.

Contract Servs. v. Allied Mold & Die, Inc., 114 Cal. Rptr. 2d 773, 777 (Cal. Ct. App. 2001); Scachitti v. UBS Fin. Servs., 831 N.E.2d 544, 557-58 (Ill. 2005). Accordingly, we address whether the plaintiffs have identified false or fraudulent claims under the seven state laws with reference to our case law interpreting the meaning of that phrase under the federal FCA.

On that question, our decision in Hutcheson, 2011 WL 2150191, controls. In Hutcheson, we declined to adopt the legal framework employed by the district court as to when a claim is false or fraudulent under the federal FCA. The plaintiff in that case alleged that, by paying kickbacks to physicians, the defendant had knowingly caused hospitals and physicians to submit false or fraudulent claims for payment to Medicare. Id. at \*2-3. We reversed the district court's holding that the plaintiff had failed to identify a false or fraudulent claim sufficient to survive Rule 12(b)(6). Id. at \*16. Medicare forms signed by the hospitals and physicians, we held, made clear that when those entities submitted claims for Medicare payment, they represented that transactions underlying the claims did not involve kickbacks prohibited by the federal Anti-Kickback Statute (AKS), 42 U.S.C. § 1320a-7b. Id. at \*13-14. We held that the plaintiffs had adequately alleged both that illegal kickbacks had underlain claims for payment and that the resulting misrepresentation was material. Id. at \*13-15.

Our analysis in Hutcheson did not employ the district court's conceptual divisions between (1) legal and factual falsity and (2) express and implied certification. Id. at \*6-7. We rejected the district court's holding that "a claim can only be impliedly false or fraudulent for non-compliance with a legal condition of payment if that condition is expressly stated in a statute or regulation." Id. at \*8. "Other means exist to cabin the breadth of the phrase 'false or fraudulent,'" we held, including the FCA's materiality and scienter requirements. Id. at \*10. We also rejected a categorical argument advanced by the defendant, and seemingly endorsed by the district court, that representations made by a submitting entity with respect to its own legal compliance "cannot encompass a precondition of payment applicable to non-submitting entities." Id. at \*10. Such a rule, we held, would impermissibly narrow the scope of liability for entities that cause other entities to submit claims that do not comply with a precondition of payment. Id. at \*11-12.

To survive this 12(b)(6) motion, Westmoreland and the state intervenors must make two showings with adequate specificity. First, they must show that the claims at issue in this litigation misrepresented compliance with a material precondition of Medicaid payment such that they were false or fraudulent. Second, they must show that the defendants knowingly caused the submission of the false or fraudulent claims, the submission of false records or

statements to get the false or fraudulent claims paid, or otherwise conspired to defraud the state by getting the false or fraudulent claims paid. On appeal, Amgen, INN, and ASD do not contest that Westmoreland and the state intervenors have met their burden as to the latter requirement; they only contest the former requirement.<sup>7</sup> The only question presented, then, is whether the claims at issue misrepresented compliance with a material precondition of payment forbidding the alleged kickbacks.

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<sup>7</sup> The defendants seek, unsuccessfully, to raise two additional issues, one of which invokes the scienter requirement.

First, the defendants argue that the district court's judgment should be affirmed because excess overfill cannot be deemed a kickback. They assert that the FDA requires some amount of overfill and that the plaintiffs have not identified any binding ceiling on the proper amount of overfill. Relatedly, Amgen asserts that in the absence of any such binding requirements, it could not have acted with the requisite scienter under the FCA. Even if these arguments are correct, and we do not decide the questions, they would not be grounds for dismissal. Westmoreland and the state defendants do not only assert that the claims at issue in this litigation were false or fraudulent on account of the alleged overfill; they also assert that the claims were false or fraudulent on account of free weekend retreats, sham honoraria, and so on.

Second, the defendants argue that we should affirm the district court's dismissal on the ground that the plaintiffs failed to plead their claims with adequate particularity under Rule 9(b). As we held in United States ex rel. Hutcheson v. Blackstone Medical, Inc., No. 10-1505, 2011 WL 2150191 (1st Cir. June 1, 2011), however, "Rule 9(b) is not a proper alternative ground for affirmance." Id. at \*6 n.8. Like the district court in Hutcheson, the district court here "never considered this argument. It is up to the court in the first instance to weigh the adequacy of the complaint for purposes of Rule 9(b) and, if appropriate, to provide 'an opportunity to correct [any] pleading deficiencies.'" Id. (quoting United States ex rel. Poteet v. Bahler Med., Inc., 619 F.3d 104, 115 (1st Cir. 2010)).



As our decision in Hutcheson makes clear, this is a fact-intensive and context-specific inquiry. Westmoreland and the state intervenors make two related arguments as to why the Medicaid claims here were false or fraudulent under the relevant state FCAs. First, they assert that "[i]t is widely recognized on both the federal and State levels that kickback schemes are fraudulent practices under Medicaid and Medicare," and that because of this the alleged kickbacks rendered the claims at issue false or fraudulent under the state FCAs.<sup>8</sup> Second, they assert that state laws, regulations, and Medicaid provider agreements make clear that the alleged kickbacks violated a precondition of Medicaid payment established in each of the seven states involved in this litigation.

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<sup>8</sup> Amgen, INN, and ASD argue that the plaintiffs waived this argument by failing to present it to the district court. They invoke the district court's observation that the "[p]laintiffs do not dispute that all of their claims rely on the false certification theory of liability," Westmoreland, 707 F. Supp. 2d at 133, and argue that under this theory of liability a claim may not be false or fraudulent absent an express or implied certification.

This argument, contrary to our decision in Hutcheson, treats the concept of certification as if it had some "paramount and talismanic significance." Hutcheson, 2011 WL 2150191, at \*7 (quoting United States ex rel. Hendow v. Univ. of Phoenix, 461 F.3d 1166, 1172 (9th Cir. 2006)) (internal quotation marks omitted). We have rejected the district court's narrow understanding of the notion of "implied certification," which it introduced in United States ex rel. Hutcheson v. Blackstone Medical, Inc., 694 F. Supp. 2d 48 (D. Mass. 2010), the day after argument on the motions to dismiss in this case. At any rate, the thrust of the argument advanced by Westmoreland and the state intervenors is the same as it was in the trial court.

We need not engage the first of these two arguments, which stretches too broadly. Even if it is generally accepted that kickbacks are a species of fraud, that cannot resolve this dispute. The question here is whether claims submitted to the seven state Medicaid programs misrepresented compliance with a precondition of payment recognized by those particular programs. So long as states have discretion over the operation of their Medicaid programs, generalities about national views as to what constitutes a precondition of Medicaid payment cannot control.<sup>9</sup> Cf. Pharma. Research & Mfrs. of Am. v. Walsh, 538 U.S. 644, 665 (2003) (noting that the states have "substantial discretion" in setting certain requirements of their Medicaid programs (quoting Alexander v. Choate, 469 U.S. 287, 303 (1985))).

Accordingly, we look to the preconditions of payment recognized under the seven state Medicaid programs involved in this litigation. The plaintiffs contend that statutes and regulations in each of the seven states make clear that claims affected by kickbacks like those alleged here are not eligible for Medicaid payment. The plaintiffs have indeed shown as much with respect to

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<sup>9</sup> Under the Medicaid Act, 42 U.S.C. §§ 1396-1396v, "the federal government provides financial support to states that establish and administer state Medicaid programs in accordance with federal law through a state plan approved by the U.S. Department of Health and Human Services." Long Term Care Pharmacy Alliance v. Ferguson, 362 F.3d 50, 51 (1st Cir. 2004). Westmoreland and the state intervenors do not assert that the federal government conditions funding to state Medicaid programs on the requirement that these programs refuse to pay claims affected by kickbacks.

the regulatory regimes in Illinois, Indiana, Massachusetts, and New York. They have also shown that provider agreements in California and New Mexico make clear that claims submitted to the Medicaid programs in each of those states may not be paid if they are influenced by kickbacks like those alleged in this litigation. Relator Westmoreland has not made such a showing under statutes, regulations, or provider agreements with respect to claims submitted to the Georgia Medicaid program.

We begin with the four states whose statutes and regulations make clear that the kickbacks alleged in this case preclude Medicaid payment.

Claims for Medicaid payment in Illinois "may be withheld . . . upon receipt by the Department [of Healthcare and Family Services] of evidence" of "fraud or willful misrepresentation under the Illinois Medical Assistance Program." Ill. Admin. Code tit. 89, § 140.44(a). Under Ill. Admin. Code tit. 89, § 140.35, titled "False Reporting and Other Fraudulent Activities," medical providers are subject to the requirements of both the federal AKS, which "prohibits kickbacks, false reporting and other fraudulent activities," id. § 140.35(b) (emphasis added), and the Illinois AKS, "pertaining to penalties for vendor fraud and kickbacks," id. § 140.35(a) (emphasis added). The Illinois AKS also extends liability to any entity that "willfully, by means of a false statement or representation, or by concealment of any material fact

or by other fraudulent scheme or device . . . obtains or attempts to obtain benefits or payments under this Code to which [it] is not entitled, or in a greater amount than that to which [it] is entitled." 305 Ill. Comp. Stat. 5/8A-3(a) (emphasis added).

Indiana law sets similar requirements. A portion of the Indiana Medicaid statute, Indiana Code §§ 12-15-1 - 12-15-44, makes clear that if the state's Medicaid office "determines that a provider has violated a Medicaid statute or rule adopted under a Medicaid statute, the office may" deny "payment to the provider for Medicaid services provided during a specified time," id. § 12-15-24-1. Another portion of the state's Medicaid statute provides that a person who "furnishes items or services to an individual for which payment is or may be made under this chapter and who solicits, offers, or receives a kickback in connection with the furnishing of the items or services or the making or receipt of the payment" commits a misdemeanor. Id. § 12-15-22-2. The state's regulations also make clear that the state's Medicaid office "may deny payment" of claims "arising out of . . . acts or practices" including (1) "Engaging in a course or conduct or performing an act deemed by the office to be improper or abusive of the Medicaid program," 405 Ind. Admin. Code § 1-1-4(a) (6) (E), and (2) "Violating any provisions of state or federal Medicaid law or any rule or regulation promulgated pursuant thereto," id. § 1-1-4(a) (6) (H).

The same applies to the regulatory regime governing the Massachusetts Medicaid program. The program "may withhold payments to a provider . . . if [it] believes that the provider has received any overpayments or committed any violations." 130 Mass. Code Regs. 450.249(B). Massachusetts law governing "Medical Assistance" provides:

Whoever solicits or receives any remuneration, including any bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind in return for purchasing, leasing, ordering or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under this chapter, or whoever offers or pays any remuneration, including any bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind to induce such person to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under this chapter shall be punished . . . .

Mass. Gen. Laws ch. 118E, § 41. Violations are punishable by "a fine of not more than ten thousand dollars," and/or "imprisonment in the state prison for not more than five years or in a jail or house of correction for not more than two and one-half years." Id.

As to the New York Medicaid program, the state's regulatory regime provides that an "overpayment includes any amount not authorized to be paid under the medical assistance program, whether paid as the result of inaccurate or improper cost reporting, improper claiming, unacceptable practices, fraud, abuse

or mistake." N.Y. Comp. Codes R. & Regs. tit. 18, § 518.1(c). The regime defines "unacceptable practice," to include "[b]ribes and kickbacks," id. § 515.2(b)(5), and lists within this category both "soliciting or receiving," id. § 515.2(b)(5)(ii) and "offering or paying," id. § 515.2(b)(5)(iv), "either directly or indirectly any payment (including any kickback, bribe, referral fee, rebate or discount), whether in cash or in kind, in return for purchasing, leasing, ordering or recommending any medical care, services or supplies for which payment is claimed under the program," id. §§ 515.2(b)(5)(ii), (iv). New York's anti-kickback statute forbids kickbacks in similar terms. See N.Y. Soc. Serv. Law §§ 366-d, -f.

The defendants make two relevant arguments that claims do not violate a precondition of payment if they are affected by kickbacks like those alleged in this litigation. First, they argue that the plaintiffs ignore the difference between conditions on participation in Medicaid and conditions on payment. This distinction, however, is not relevant to the provisions just described, which explicitly refer to payment. Second, they argue that, even if these provisions establish that kickbacks like those alleged here violate a precondition of payment, they do not expressly include kickbacks within definitions of "false claims," compare N.Y. Comp. Codes R. & Regs. tit. 18, § 515.2(b)(1) with id. § 515.2(b)(5), which they assert are more typically described as claims whose falsity increases the dollar amount claimed, cf. N.Y.

Comp. Codes R. & Regs. tit. 18, § 515.2(b)(1). The language defendants cite, however, does not purport to limit the definition of a false or fraudulent claim; it merely provides examples of situations that would give rise to false or fraudulent claims.

Each of these four state regulatory regimes make clear that claims are not entitled to Medicaid payment if they are affected by kickbacks like those alleged here. Given that the absence of such kickbacks is a precondition of being entitled to payment under these Medicaid programs, the reimbursement claims submitted to the four programs "represented that there had been compliance with a material precondition of payment that had not been met." Hutcheson, 2011 WL 2150191, at \*13; see also United States v. Sci. Applications Int'l Corp., 626 F.3d 1257, 1268-69 (D.C. Cir. 2010). Accordingly, the plaintiffs have stated claims under these four state FCAs.

We now turn to the argument that the claims submitted to California and New Mexico violated preconditions of Medicaid payment in those states because of the alleged kickbacks. We bypass the argument that statutes and regulations in the two states

make this clear,<sup>10</sup> as the plaintiffs have identified provider agreements in the two states that are more than sufficient.

As to California's provider agreement, which providers must sign to participate in the state's Medicaid program, the first page requires that providers agree "to comply with all applicable provisions of Chapters 7 and 8 of the Welfare and Institutions Code." Chapter 7 of the code includes California's anti-kickback statute, which applies to:

Any person who solicits or receives any remuneration, including, but not restricted to, any kickback, bribe, or rebate, directly or indirectly, overtly or covertly, in cash or in valuable consideration of any kind . . . in return for the purchasing, leasing, ordering, or arranging for or recommending the purchasing, leasing, or ordering of any goods, facility, service or merchandise for which payment may be made, in whole or in part, under this chapter or Chapter 8.

Cal. Welf. & Inst. Code § 14,107.2(a).

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<sup>10</sup> Under California law, the plaintiffs have noted that the state Medicaid program may withhold payment when it receives evidence "of fraud or willful misrepresentation by a provider as defined in Section 14043.1." Cal. Welf. & Inst. Code § 14107(a)(2). Section 14043.1 defines "fraud" as "intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself or herself or some other person. It includes any act that constitutes fraud under applicable federal or state law." Id. § 14043.1(I). They have also identified a regulation that lists fraud as grounds for suspension from California's Medicaid program. See id. § 14123. Westmoreland has not identified any relevant provisions of New Mexico law other than the state's FCA and anti-kickback statute.



As to New Mexico's provider agreements,<sup>11</sup> which again providers must sign to participate in the state's Medicaid program, Article VIII is entitled "Imposition of Sanctions for Fraud or Misconduct." This Article states:

If the provider obtains an excess payment or benefit willfully, by means of false statement, representation, concealment of any material fact, or other fraudulent scheme or devise with intent to defraud, criminal sentences and fines and/or civil monetary penalties shall be imposed pursuant to, but not limited to, the Medicaid Fraud Act, NMSA 1978, §§ 30-44-1 et seq., 42 U.S.C. § 1320a-7b, and 42 C.F.R. § 455.23.

As this language makes clear, both the provider agreements and New Mexico's anti-kickback statute denote kickbacks as a form of fraud. New Mexico's Medicaid Provider Act, N.M. Stat. Ann. §§ 27-11-1 et seq., moreover, provides that the state Medicaid program may suspend or revoke a provider agreement if a provider has "fraudulently procured or attempted to procure any benefit from medicaid," id. §§ 27-11-3(B)(6), (C)(3). The state's provider agreements make clear that violations of the state's Medicaid Provider Act warrant their suspension or revocation.

It is true that these provider agreements speak to the compliance of the providers rather than third parties like Amgen,

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<sup>11</sup> Westmoreland has introduced two provider agreements from New Mexico, one applicable to individual providers within a group (Form 312) and the other applicable to groups, organizations, or individual providers to whom payment may be made (Form 335). These two agreements are not relevantly different.

INN, and ASD, but this is of no moment as to whether they rendered the relevant claims false or fraudulent. The agreements amount to a representation of compliance with the relevant anti-kickback statutes, and the plaintiffs assert that the alleged kickbacks rendered this representation incorrect. The defendants again assert that this conclusion ignores a distinction between conditions of Medicaid payment and conditions of Medicaid participation. We again do not agree that this distinction is relevant. The California agreement requires providers to represent compliance with the state's anti-kickback statute, and the New Mexico agreement requires providers to acknowledge that non-compliance with anti-kickback laws vitiates a provider's ability to get its claims paid.<sup>12</sup>

With respect to Georgia, however, the plaintiff relator has not identified any materials that make clear that claims affected by kickbacks may violate a precondition of payment under the state's Medicaid program. Westmoreland argues that both Georgia case law and Medicaid provider agreements make such a precondition clear. Each of these arguments fail.

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<sup>12</sup> Amgen argues as well that the plaintiffs' failure to prove that the providers acted with scienter "necessarily dooms" the states' assertion that the government could disavow the providers' Medicaid contracts. In Hutcheson, we held that FCA liability does not depend on "whether the submitting entity knew or should have known about a non-submitting entity's unlawful conduct." Hutcheson, 2011 WL 2150191, at \*11. At any rate, the plaintiffs do allege that the providers acted with scienter in accepting the alleged kickbacks.

As to Georgia case law, Westmoreland cites a judicial construction of Ga. Code Ann. § 49-4-146.1(b)(1)(C). That provision states that "It shall be unlawful,"

(1) For any person or provider to obtain, attempt to obtain, or retain for himself, herself, or any other person any medical assistance or other benefits or payments under this article, or under a managed care program operated, funded, or reimbursed by the Georgia Medicaid program, to which the person or provider is not entitled, or in an amount greater than that to which the person or provider is entitled, when the assistance, benefit, or payment is obtained, attempted to be obtained, or retained, by: . . . (C) Any fraudulent scheme or device[.]

Ga. Code Ann. § 49-4-146.1(b). Westmoreland argues that Georgia case law recognizes that kickbacks are a "fraudulent scheme or device" for purposes of this statute, citing one case: Culver v. State, 562 S.E.2d 201, 206-07 (Ga. Ct. App. 2002), rev'd on other grounds sub nom. State v. Kell, 577 S.E.2d 551 (Ga. 2003). That case, however, does not refer to kickbacks, and instead concerned a scheme to bill the state Medicaid program for unnecessary drug tests, at inflated prices, through a sham arrangement.

As to Georgia's Medicaid provider agreement, Westmoreland presents the following argument. The first page of the form states, "Provider shall comply with all of the Department's requirements applicable to the category(ies) of service in which Provider participates under this Statement of Participation, including Part I, Part II and the applicable Part III manuals."

The Part I manual, she argues, includes an anti-kickback prohibition as one of the State's "general conditions of participation" in the Medicaid program. The purported anti-kickback provision states that providers shall

[n]ot contact, provide gratuities or advertise "free" services to Medicaid or PeachCare for Kids members for the purpose of soliciting members' requests for services . . . . Any offer or payment of remuneration, whether direct, indirect, overt, covert, in cash or in kind, in return for the referral of a Medicaid or PeachCare for Kids member is also prohibited.

Although this provision may identify some preconditions of payment under Georgia's Medicaid program, it is hardly relevant to the alleged kickbacks in this case. The plaintiffs assert that the kickbacks encouraged the use of Aranesp; they do not speak at all about payments in exchange for referrals of patients.

It may be that under Georgia's Medicaid program it is a precondition of payment that claims not be affected by kickbacks like the kickbacks alleged in this case. Westmoreland has not identified any authority, however, that makes this clear. It bears emphasis that Georgia, unlike the other six states involved in this litigation, does not have a state law analogue to the federal AKS. In the absence of any authority on this point, Westmoreland cannot establish that the claims for Medicaid payment submitted to Georgia's Medicaid program were false or fraudulent. Accordingly,

she cannot state a claim against Amgen, INN, or ASD under Georgia's FCA.

III.

For the foregoing reasons, we reverse the district court's dismissal of plaintiffs' claims under the state FCAs in California, Illinois, Indiana, Massachusetts, New Mexico, and New York. We affirm the district court's dismissal of the plaintiffs' claims under Georgia's FCA. Costs shall be awarded to the prevailing parties on each of the claims.

So ordered.