PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 15-3805

UNITED STATES OF AMERICA, ex rel.
GERASIMOS PETRATOS,

GERASIMOS PETRATOS, ex rel. UNITED STATES OF AMERICA; STATE OF CALIFORNIA; STATE OF COLORADO; STATE OF CONNECTICUT; STATE OF DELAWARE; STATE OF FLORIDA; STATE OF GEORGIA; STATE OF HAWAII; STATE OF ILLINOIS; STATE OF INDIANA; STATE OF LOUISIANA; STATE OF MARYLAND; COMMONWEALTH OF MASSACHUSETTS; STATE OF MICHIGAN; STATE OF MINNESOTA; STATE OF MONTANA; STATE OF NEVADA; STATE OF NEW HAMPSHIRE; STATE OF NEW JERSEY; STATE OF NEW MEXICO; STATE OF NEW YORK; STATE OF NORTH CAROLINA; STATE OF OKLAHOMA; STATE OF RHODE ISLAND; STATE OF TENNESSEE; STATE OF TEXAS; COMMONWEALTH OF VIRGINIA; DISTRICT OF COLUMBIA,

Appellants

v.

GENENTECH INC; ROCHE GROUP;
HOFFMAN LA ROCHE, INC.; ROCHE HOLDINGS, LTD.;
F HOFFMAN - LA ROCHE, LTD

On Appeal from the United States District Court
for the District of New Jersey
(D.C. No. 2-11-cv-03691)
District Judge: Honorable Madeline C. Arleo

Argued November 1, 2016
Before: HARDIMAN and SCIRICA, *Circuit Judges*,
and ROSENTHAL,[*] *District Judge*.

(Filed: May 1, 2017)

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[*] The Honorable Lee H. Rosenthal, United States District Judge for the Southern District of Texas, sitting by designation.

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OPINION OF THE COURT

HARDIMAN, *Circuit Judge*.

This appeal arising under the False Claims Act involves a multi-billion dollar cancer drug, Avastin, which was developed by Appellee Genentech. Relator Gerasimos Petratos, who was head of healthcare data analytics for Genentech, filed a *qui tam* action soon after leaving the company. He alleged that Genentech suppressed data that caused doctors to certify incorrectly that Avastin was "reasonable and necessary" for certain at-risk Medicare patients. The District Court dismissed Petratos's suit for failure to state a claim. Although we disagree with the District Court's grounds for dismissal, we will affirm because Petratos failed to satisfy the False Claims Act's materiality requirement.

I

A

A widely prescribed cancer drug that has accounted for $1.13 billion a year in Medicare reimbursements, Avastin is approved by the FDA to treat several types of cancer. Petratos alleged that Genentech concealed information about Avastin's health risks. Specifically, he claimed the company ignored and suppressed data that would have shown that Avastin's side effects for certain patients were more common and severe than reported. According to Petratos, such analyses would have required the company to file adverse-

event reports with the FDA, and could have resulted in changes to Avastin's FDA label. Genentech also allegedly suppressed information regarding Avastin's side effects for patients with renal failure despite a request to disclose that information by a "Key Opinion Leader," a recognized industry expert who "influence[s] peers' medical practice, including but not limited to prescribing behavior." John Mack, *A KOL by Any Other Name*, 14-03 Pharm. Mktg. News 1, 1 (2015).

Petratos claimed Genentech's data suppression was part of a formal campaign, dubbed "Optimizing Data Value," during which the company avoided certain analyses and data sets that might yield negative results to mitigate its "business risk." App. 324–26. Petratos asserted that he tried to bring the safety risks inherent in this strategy to the attention of upper management, but was told "to stop any further work in [the] area," App. 318, and had his job "threatened," App. 314.

As a consequence of Genentech's data-suppression strategy, Petratos claimed the company caused physicians to submit Medicare claims that were not "reasonable and necessary." In the opinion of one oncologist, if Genentech had properly disclosed Avastin's side-effects for certain at-risk patients, "the standard of care would have been to prescribe a lower dose of Avastin, a lower frequency of doses, or no dose at all." App. 341.

B

Initially filed in 2011, this case was heard by three judges of the United States District Court for the District of New Jersey. Soon before his retirement, Judge Cavanaugh dismissed Petratos's initial complaint in part, but granted a

stay of the order so Petratos could amend his complaint. The case was reassigned to Judge Wigenton, who rejected Genentech's argument that an amendment would be futile and held that Petratos "sufficiently alleged causes of action" under the False Claims Act. App. 56. Finally, the case was transferred to Judge Arleo, who took a different tack than Judge Wigenton and reasoned that "medically 'reasonable and necessary' is a determination made by the relevant agency, not individual doctors." App. 16–17. Because Petratos's theory relied on the doctors as part of the "reasonable and necessary" determination, Judge Arleo deemed the complaint fatally deficient and dismissed all claims. App. 18–19. Petratos filed this timely appeal.

II

The District Court had subject-matter jurisdiction over Petratos's federal claim under 28 U.S.C. § 1331 and supplemental jurisdiction over his state-law claims under 28 U.S.C. § 1367. We have appellate jurisdiction under 28 U.S.C. § 1291. We "exercise plenary review of the District Court's order granting appellees' motion to dismiss for failure to state a claim." *United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 302 (3d Cir. 2011). We review for abuse of discretion both the District Court's decision to reconsider a predecessor judge's ruling, *Fagan v. City of Vineland*, 22 F.3d 1283, 1290 (3d. Cir. 1994), and its denial of leave to amend the complaint, *United States ex rel. Schumann v. Astrazeneca Pharms. L.P.*, 769 F.3d 837, 849 (3d Cir. 2014).

III

A

Petratos's claims implicate three interlocking federal schemes: the False Claims Act, Medicare reimbursement, and FDA approval. We begin by briefly outlining each scheme.

The False Claims Act is meant "to reach all types of fraud . . . that might result in financial loss to the Government." *Cook Cty. v. United States ex rel. Chandler*, 538 U.S. 119, 129 (2003) (quoting *United States v. Neifert-White Co.*, 390 U.S. 228, 232 (1968)). A False Claims Act violation occurs when a person "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A). A claim is legally false when it does not comply "with a statute or regulation the compliance with which is a condition for Government payment." *Wilkins*, 659 F.3d at 305.[1]

The allegedly false claims in this case were submitted to the Medicare program, which reimburses the health care costs incurred by program beneficiaries. The Medicare statute provides that "no payment may be made" for items and services that "are not reasonable and necessary for the

[1] A claim may be factually or legally false. *Wilkins*, 659 F.3d at 305. "A claim is factually false when the claimant misrepresents what goods or services that it provided to the Government." *Id.* Although Petratos halfheartedly argues that the claims at issue are factually false, he is incorrect. There is no dispute that the physicians actually provided the claimed good (Avastin) in the claimed doses.

diagnosis and treatment of illness or injury." 42 U.S.C. § 1395y(a)(1)(A). Because a claim can be false if it does not comply with statutory conditions for payment, the claims at issue here are false if Avastin was not "reasonable and necessary." *See id.*

One important factor considered by the Centers for Medicare and Medicaid Services (CMS) to determine whether a prescribed drug is "reasonable and necessary" is whether it has received FDA approval. Indeed, CMS guidance explains that "with some exceptions, a drug must have final marketing approval from the FDA to be considered 'reasonable and necessary.'" Medicare Benefit Policy Manual, CMS Pub. 100-2, ch. 1, § 30 (Part A). In most instances, the drug must also be used for a "medically accepted indication"—meaning that it has been deemed appropriate for the particular treated condition. 42 U.S.C. § 1395x(t)(2). An indication is "medically appropriate" if it has been approved by the FDA or supported by research in certain authoritative compendia. *See id*.; 42 C.F.R. § 414.930.

B

A False Claims Act violation includes four elements: falsity, causation, knowledge, and materiality. *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 1996 (2016) (materiality); *Wilkins*, 659 F.3d at 304–05 (falsity, causation, knowledge). The District Court focused on the falsity element, concluding that the disputed claims were not false because they were "reasonable and necessary" as a matter of law.

The District Court reached its conclusion by conflating two separate standards from the Medicare statute. First, the

Court noted that § 1395x provides that a drug is used for a "medically accepted indication" when it has been approved by the FDA or listed in authoritative compendia. 42 U.S.C. § 1395x(t)(2)(A). It then adopted the rule from another district court case that this "medically accepted" standard is coterminous with the "reasonable and necessary" standard in § 1395y(a)(1)(A). App. 14 (citing *United States ex rel. Simpson v. Bayer Corp.*, 2013 WL 4710587, at *3 (D.N.J. Aug 30, 2013)). Consequently, the District Court held that because "Avastin is approved by the FDA and supported by compendia listings, . . . [Petratos cannot] argue that prescriptions [for] Avastin were not 'reasonable and necessary.'" App. 14 (citations omitted) (second alteration in original). The Court explained that its decision aligns with the principle that "'reasonable and necessary' is a determination made by the relevant agency, not individual doctors." App. 17.

We disagree with the District Court's reading of the statute. In our view, its analysis was premised on a false choice, namely, that "this dispute comes down to whether medically 'reasonable and necessary' is assessed by doctors individually or is defined by the regulatory scheme." App. 16. But these two options do not account for all possibilities. As Petratos and the United States argue, a third possibility exists: that the "reasonable and necessary" determination is a process involving the FDA, CMS, *and* individual doctors. Indeed, CMS guidance, other Medicare provisions and regulations, and canons of statutory construction lead us to conclude that this is the best reading of the statute.

First, CMS guidance makes clear that the "reasonable and necessary" determination does not end with FDA approval. The claim at issue must also be "reasonable and

necessary for [the] *individual patient*" based on "accepted standards of medical practice and the medical circumstances of the *individual case*." Medicare Benefit Policy Manual, ch. 15, § 50.4.3 (emphases added). The Manual provides examples of when a drug treatment could be approved by the FDA and used for a medically accepted indication, but still not be "reasonable and necessary." For example, a drug treatment is not "'reasonable and necessary' for Medicare Part B if standard medical practice indicates that oral administration (as opposed to injection) 'is effective and is an accepted or preferred method of administration,' or if the administration of injections 'exceed[s] the frequency or duration of injections indicated by accepted standards of medical practice.'" United States Br. 21 (quoting Medicare Benefit Policy Manual, ch. 15, § 50.4.3).

Second, other Medicare provisions and regulations underscore the critical role of the physician in Medicare's payment and reimbursement scheme. The regulations provide that "[t]he physician has a major role in determining utilization of health services furnished by providers. The physician decides upon admissions, orders tests, drugs, and treatments, and determines the length of stay." 42 C.F.R. § 424.10(a). Under Medicare Parts A and B, it usually is "a condition for Medicare payment that a physician certify the necessity of the services and, in some instances, recertify the continued need for those services." *Id.* Indeed, physicians prescribing Avastin often must submit CMS Form 1500 along with a claim for reimbursement, wherein the doctor certifies that the drug was "medically necessary and personally furnished by me or . . . my employee under my direct supervision." United States Br. 29–30 (quoting CMS Form 1500). In addition, the Medicare statute contains a separate

section that outlines the obligations of physicians when providing services to plan beneficiaries, including the obligation to provide services "economically and only when, and to the extent, medically necessary." 42 U.S.C. § 1320c-5(a).

Third, principles of statutory construction show that "medically accepted" and "reasonable and necessary" are not coterminous. "[T]he use of different words or terms within a statute demonstrates that Congress intended to convey a different meaning for those words." *Race Tires Am., Inc. v. Hoosier Racing Tire Corp.*, 674 F.3d 158, 165 (3d Cir. 2012) (citation omitted). And once this erroneous premise is removed from the District Court's decision, its analysis falters. *See* App. 14 (reasoning that because "the 'reasonable and necessary' standard [is] coterminous with the 'medically accepted' requirement, . . . [Petratos cannot concede that] Avastin is approved by the FDA and supported by compendia listings" and "still argue that prescriptions [for] Avastin were not reasonable and necessary").

The cases cited by the District Court do not hold that the "reasonable and necessary" decision is decided exclusively by federal agencies. Rather, these cases show that federal agencies retain ultimate control over the decision and that Government approval is a necessary component of the determination. *See, e.g., United States ex rel. Bodnar v. Secretary of Health & Human Servs.*, 903 F.2d 122, 125 (2d Cir. 1990). And none of the cited cases purports to eliminate the treating physician from the process. Indeed, other Courts of Appeals have recognized that "Congress intends the physician to be a key figure in determining what services are needed and consequently reimbursable." *Goodman v.*

Sullivan, 891 F.2d 449, 450 (2d Cir. 1989) (citing *Rush v. Parham*, 625 F.2d 1150, 1157 (5th Cir. 1980)).

From a practical perspective, this multi-step interpretation makes sense. CMS and the FDA are best positioned to make high-level policy decisions— such as issuing national coverage determinations and drug approvals. These general approvals demarcate what treatments can be considered "reasonable and necessary," and are thus a necessary condition for reimbursement. Meanwhile, the doctors are best suited to evaluate each patient and determine whether a treatment is "reasonable and necessary *for [that] individual patient*." *See* Medicare Benefit Policy Manual, ch. 15, § 50.4.3 (emphasis added). For example, Avastin is approved by the FDA to treat patients with metastatic colorectal cancer and such prescriptions are reimbursable by CMS. But if a doctor determined that a colorectal cancer patient had five hours to live and would best be treated with palliative care, then prescribing Avastin in that situation may not be "reasonable and necessary."

C

Although we disagree with the District Court's reasoning, we may affirm its judgment on any ground supported by the record. *See, e.g.*, *Guthrie v. Lady Jane Collieries, Inc.*, 722 F.2d 1141, 1145 n.1 (3d Cir. 1983). Our review of the record leads us to conclude that Petratos cannot establish materiality, which the False Claims Act defines as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money." 31 U.S.C. § 3729(b)(4).

Just last year in *Universal Health Services v. United States ex rel. Escobar*, the Supreme Court confirmed that "[a] misrepresentation about compliance with a statutory, regulatory, or contractual requirement must be material to the Government's payment decision in order to be actionable under the False Claims Act." 136 S. Ct. 1989, 1996 (2016). The Court described this standard as "demanding" and "rigorous," *id.* at 2002–03, and explained that a material misrepresentation is one that goes "to the very essence of the bargain," *id* at 2003 n.5 (citations omitted). This requirement helps ensure that the False Claims Act does not become "an all-purpose antifraud statute or a vehicle for punishing garden-variety breaches of contract." *Id.* at 2003 (citation and internal quotation marks omitted).

The Supreme Court also provided guidance as to how the materiality requirement should be enforced. It explained that a misrepresentation is not material "merely because the Government designates compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment . . . [or because] the Government would have the option to decline to pay if it knew of the defendant's noncompliance." *Id.* Materiality may be found where "the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement." *Id.* On the other hand, it is "very strong evidence" that a requirement is not material "if the Government pays a particular claim in full despite its actual knowledge that certain requirements were

violated." *Id.* Finally, materiality "cannot be found where noncompliance is minor or insubstantial." *Id.*[2]

Petratos's allegations do not meet this high standard. As the District Court noted: "there are no factual allegations showing that CMS would not have reimbursed these claims had these [alleged reporting] deficiencies been cured." App. 18. Petratos does not dispute this finding, which dooms his case. Simply put, a misrepresentation is not "material to the *Government's payment decision*," when the relator concedes that the Government would have paid the claims with full knowledge of the alleged noncompliance. *See Universal Health Servs.*, 136 S. Ct. at 1996 (emphasis added). Similarly, we think that where a relator does not plead that knowledge of the violation could influence the Government's decision to pay, the misrepresentation likely does not "have[] a natural tendency to influence . . . payment," as required by the statute. *See* 31 U.S.C. § 3729(b)(4). At a minimum, this would be "very strong evidence" that the misrepresentation was not material. *Universal Health Servs.*, 136 S. Ct. at 2003.

The Supreme Court's guidance in *Universal Health Services* also militates against a finding of materiality. The mere fact that § 1395y is a condition of payment, without more, does not establish materiality. *See id.* In addition, Petratos not only fails to plead that CMS "consistently refuses to pay" claims like those alleged, *see id.*, but essentially concedes that CMS would *consistently reimburse* these claims with full knowledge of the purported noncompliance.

[2] The Court also rejected the argument that materiality is "too fact intensive" to allow dismissal at the pleading stage, explaining that plaintiffs must "plead[] facts to support allegations of materiality." *Id.* at 2004 n.6.

Nor has he cited to a single successful claim under § 1395y involving drugs prescribed for their on-label uses or a court decision upholding such a theory.

Petratos's allegations are much like the sort of "minor or insubstantial" noncompliance that the Supreme Court explained should not be litigated under the False Claims Act. *See id.* Petratos does not claim that Genentech's safety-related reporting violated any statute or regulation. He acknowledges that the FDA would not "have acted differently had Genentech told the truth." App. 64. And as we have explained, he does not dispute that CMS would reimburse these claims even with full knowledge of the alleged reporting deficiencies.

In fact, Petratos admits that he disclosed "material, non-public evidence of Genentech's campaign of misinformation" to the FDA and Department of Justice in 2010 and 2011. App. 337. Since that time, the FDA has not merely continued its approval of Avastin for the at-risk populations that Petratos claims are adversely affected by the undisclosed data, but has *added* three more approved indications for the drug. Nor did the FDA initiate proceedings to enforce its adverse-event reporting rules or require Genentech to change Avastin's FDA label, as Petratos claims may occur. And in those six years, the Department of Justice has taken no action against Genentech and declined to intervene in this suit.

Since Petratos concedes that the expert agencies and government regulators have deemed these violations insubstantial (or at least would do so if made aware), we do not think it appropriate for a private citizen to enforce these regulations through the False Claims Act. *See United States v.*

Sanford-Brown, Ltd., 840 F.3d 445, 447 (7th Cir. 2016) (dismissing False Claims Act complaint on materiality grounds because "federal agencies in this case have already examined [the claims] multiple times over and concluded that neither administrative penalties nor termination was warranted" (citations and internal quotation marks omitted)). After all, the False Claims Act is not "a blunt instrument to enforce compliance with all . . . regulations." *Wilkins*, 659 F.3d at 307 (citation omitted).

Petratos's arguments to the contrary are unpersuasive. First, he claims that materiality is established because "if physicians would have prescribed no or less Avastin, the Government would have paid less claims." Reply Br. 4. In other words, Petratos argues that materiality can be established by proving that the alleged fraud was the "but for" cause of the submitted claim. Petratos's argument conflates materiality with causation, a separate element of a False Claims Act cause of action. *See Wilkins*, 659 F.3d at 304–05. Collapsing the materiality analysis into a causation inquiry would render the materiality element "surplusage" and fail to "give effect . . . to every clause and word of [the] statute," which we are loath to do. *Tavarez v. Klingensmith*, 372 F.3d 188, 190 (3d Cir. 2004) (citations and internal quotation marks omitted). And even the causation element cannot be met merely by showing "but for" causation. *See United States ex rel. Hendow v. Univ. of Phoenix*, 461 F.3d 1166, 1174 (9th Cir. 2006) (explaining that the false claim must be "*integral* to a causal chain leading to payment" (citations omitted)); United States Br. 27 ("The United States does not contend that a claim is necessarily false or fraudulent because an antecedent fraud was a "but for" cause of the claim being submitted."); *cf. Paroline v. United States*, 134 S. Ct. 1710,

1720 (2014) ("Proximate cause is a standard aspect of causation in . . . the law of torts"). If a "but for" causation theory is insufficient to meet the *causation* element—where that type of proof is more properly directed—it follows that it should be insufficient to demonstrate materiality.

Petratos next argues that it is incorrect to focus our materiality inquiry on the Government's payment decision. Rather, he claims that "the relevant question is whether Genentech's fraudulent misrepresentations were material to the *physicians'* determinations." Reply Br. at 13. Petratos points to *Universal Health Services*, where the Supreme Court quoted a treatise to explain that "materiality 'look[s] to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation.'" *Universal Health Servs.*, 136 S. Ct. at 2002 (quoting 26 R. Lord, Williston on Contracts § 69:12, p. 549 (4th ed. 2003)). Petratos reads this language to mean that in indirect-causation cases—where the fraud is first directed at an intermediary who then unwittingly forwards it to the Government for payment—we look solely to the *initial* recipient of the misrepresentation and not to the Government.

We disagree. The full context of the quotation shows that when the Court wrote "the recipient of the alleged misrepresentation," it was referring to the Government, not the initial recipient. *See id.* This makes sense because the Government will always be the recipient of the misrepresentation in the False Claims Act context. *See Wilkins*, 659 F.3d at 304–05 (explaining that a plaintiff must prove that "the defendant presented or caused to be presented *to an agent of the United States* a claim for payment" (emphasis added) (citation omitted)). Indeed, when the Court turned to materiality in the False Claims Act–specific context, it exclusively referred to the Government as the ultimate

recipient of the misrepresentation. *Universal Health Servs.*, 136 S. Ct. at 1996 ("A misrepresentation about compliance with a statutory, regulatory, or contractual requirement *must be material to the Government's payment decision* in order to be actionable under the False Claims Act." (emphasis added)).

Our sister courts have interpreted *Universal Health Services* the same way. *See, e.g.*, *United States ex rel. Garzione v. PAE Gov't Servs., Inc.*, 2016 WL 6518539, at *1 (4th Cir. Nov. 3, 2016) ("The relevant question is whether the defendant knowingly violated a requirement that the defendant knows is material to the government's decision to pay a claim."); *United States ex rel. Escobar v. Universal Health Servs., Inc.*, 842 F.3d 103, 109 (1st Cir. 2016) ("In order for False Claims Liability to attach, these misleading omissions must be material to the government's decision to pay the claim."); *United States v. Sanford–Brown, Ltd.*, 840 F.3d 445, 447 (7th Cir. 2016) (dismissing claim where there was "no evidence that the government's decision to pay [the claim] would likely or actually have been different had it known of [the violation]"). Besides, it would make little practical sense to give the doctors' materiality determinations dispositive weight. Because the False Claims Act was passed to protect the federal treasury, *United States v. McNinch*, 356 U.S. 595, 599 (1958), and since the Government decides on payment, *Universal Health Servs.*, 136 S. Ct. at 1996, it is the Government's materiality decision that ultimately matters.

By attempting to focus our inquiry solely on the physician's materiality determination, Petratos again tries to pass off restyled causation arguments as proof of materiality. The alleged fraud's effect on physicians is relevant to the extent that it caused claims eventually to reach CMS. That is,

evidence of how the claim makes its way to the government should be considered under the causation analysis, while the materiality analysis begins after a claim has been submitted. The materiality inquiry, in asking whether the government's payment decision is affected, assumes that the claim has in fact reached the government. *See Universal Health Servs.*, 136 S. Ct. at 1996.

The Supreme Court's treatment of indirect-causation cases confirms this result. In *United States ex rel. Marcus v. Hess*, the defendant contractors submitted fraudulent bids to local governments for various projects funded by the federal government. 317 U.S. 537, 542–43 (1943). Even though the fraud was not directed at the federal government in the first instance, the Court held the defendants liable because their "fraud did not spend itself with the execution of the contract," but rather "taint[ed]" the claims paid by the United States. *Id.* at 543–44. In other words, if the fraud had deceived only the initial recipients (and not the government), then the defendants would not have been liable under the False Claims Act. Therefore, the alleged fraud must affect the United States' payment decision to be actionable. Following this logic, our focus here should not be whether the alleged fraud deceived the prescribing physicians, but rather whether it affected CMS's payment decision. Because it did not, Petratos's claim fails.[3]

[3] Having reached this conclusion, it follows that Petratos's two related claims also fail. Petratos's state law claims are, as he notes, dependent on the viability of his FCA claim. *See* Petratos Br. 54 (arguing that because "dismissal of the FCA claims was in error, the dismissal of the other claims should be reversed."). The same is true for his "reverse" FCA

In holding that Petratos did not sufficiently plead materiality, we now join the many other federal courts that have recognized the heightened materiality standard after *Universal Health Services*. *See, e.g.*, *United States ex rel. Kelly v. Serco, Inc.*, 2017 WL 117154, at *6–7 (9th Cir. Jan. 12, 2017); *Sanford-Brown*, 840 F.3d at 447; *City of Chicago v. Purdue Pharma L.P.*, 2016 WL 5477522, at *15 (N.D. Ill. Sept. 29, 2016); *United States ex rel. Scharff v. Camelot Counseling*, 2016 WL 5416494, at *8 (S.D.N.Y. Sept. 28, 2016); *United States v. N. Adult Daily Health Care Ctr.*, 205 F. Supp. 3d 276, 295–96 (E.D.N.Y. 2016); *Knudsen v. Sprint Commc'ns Co.*, 2016 WL 4548924, at *12–13 (N.D. Cal. Sept. 1, 2016); *cf. Escobar*, 842 F.3d at 111 (finding FCA violations material where those violations were "as central to the bargain as the United States ordering and paying for a shipment of guns, only to later discover that the guns were incapable of firing").

IV

We turn next to what is essentially a procedural challenge. Petratos claims that Judge Arleo erred by granting Genentech's motion to dismiss in light of Judge Wigenton's earlier finding that Petratos had "sufficiently alleged causes of action." App. 56. He alleges that Judge Arleo did not

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claims. A reverse false claim occurs when a defendant acts improperly to avoid paying an "obligation" owed to the government. 31 U.S.C. § 3729(a)(1)(G). But Genentech did not violate the FCA and, as the District Court noted, Petratos "provides no other basis for reverse false claims liability." App. 21.

satisfy our rule that absent "'exceptional circumstances,' 'judges of co-ordinate jurisdiction sitting in the same court and in the same case should not overrule the decisions of each other.'" Petratos Br. 22 (quoting *Hayman Cash Register Co. v. Sarokin*, 669 F.2d 162, 168 (3d Cir. 1982) (citation omitted)).

Though Petratos does not cite it by name in his opening brief, he invokes the "law of the case" doctrine: a judicial rule of practice meant to "maintain consistency and avoid reconsideration of matters once decided during the course of a single continuing lawsuit." 18 Charles A. Wright & Arthur R. Miller, *Federal Practice and Procedure* § 4478 (2d ed.). The law of the case doctrine is unhelpful to Petratos because it "does not limit the power of trial judges to reconsider their [own] prior decisions." *Williams v. Runyon*, 130 F.3d 568, 573 (3d Cir. 1997). Therefore, "[i]nterlocutory orders . . . remain open to trial court reconsideration, and do not constitute the law of the case." *Perez-Ruiz v. Crespo-Guillen*, 25 F.3d 40, 42 (1st Cir. 1994). And the grant of a leave to amend is an interlocutory order. *Powers v. Southland Corp.*, 4 F.3d 223, 229 (3d Cir. 1993). Therefore, Judge Wigenton's order granting leave to amend was not the law of the case—and Judge Arleo was within her discretion to disagree with it.

That this case was transferred between judges does not change the result. Although the doctrine provides that "a successor judge should not lightly overturn decisions of [her] predecessors in a given case," "it does not limit the power of trial judges from reconsidering issues previously decided by a predecessor judge from the same court." *Fagan*, 22 F.3d at 1290; *see also Rimbert v. Eli Lilly & Co.*, 647 F.3d 1247, 1252 (10th Cir. 2011) (explaining that the "law of the case

doctrine has no bearing on the revisiting of interlocutory orders, even when a case has been reassigned from one judge to another").

V

Finally, Petratos argues that the District Court abused its discretion because it denied his request for leave to amend without explanation. But there was nothing to explain. Petratos offered no reason why leave to amend was appropriate or what his amendment would have looked like. His cursory request for leave was contained in the final clause of his brief opposing Genentech's motion to dismiss. *See* App. 99 ("Relator respectfully requests that this Court deny Genentech's motion in its entirety or, alternatively, that Relator be granted leave to amend."). This threadbare recital was insufficient. "While Federal Rule 15(a) provides that leave to amend shall be freely given when justice so requires, a mere request in [a brief in] opposition to a motion to dismiss—without any indication of the particular grounds on which amendment is sought—does not constitute a motion within the contemplation of Rule 15(a)." *U.S. ex rel. Williams v. Martin-Baker Aircraft Co*., 389 F.3d 1251, 1259 (D.C. Cir. 2004) (citation omitted). Because Petratos did not properly seek leave to amend in the District Court, we will not consider this argument on appeal.

* * *

Petratos's allegations may be true and his concerns may be well founded—but a False Claims Act suit is not the appropriate way to address them. He concedes that Genentech followed all pertinent statutes and regulations. If those laws and regulations are inadequate to protect patients, it falls to

the other branches of government to reform them. We will affirm the judgment of the District Court.