No. 17-15111

United States Court of Appeals for the Ninth Circuit

SCOTT ROSE, Attorney; MARY AQUINO; MITCHELL NELSON; LUCY STEARNS,

Plaintiffs-Appellees,

– v. –

STEPHENS INSTITUTE, DBA Academy of Art University,

Defendant-Appellant.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA, OAKLAND IN CASE NO. 4:09-CV-05966-PJH, HONORABLE PHYLLIS J. HAMILTON

BRIEF FOR *AMICUS CURIAE* NATIONAL NURSES UNITED ("NNU") – CALIFORNIA NURSES ASSOCIATION, *ET AL.* IN SUPPORT OF PLAINTIFFS-APPELLEES

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure, *amicus curiae* the National Nurses United – California Nurses Association submits the following corporate disclosure statement.

The California Nurses Association and its parent organization, National Nurses United are professional nursing associations and labor organizations recognized as nonprofit organizations under section 501(c)(5) of the Internal Revenue Code. Neither have publicly issued stock that is held by a corporation.

Dated: August 7, 2017

/s/ Justin S. Brooks

Counsel for *Amicus Curiae* the National Nurses United – California Nurses Association ("NNU") *et al*.

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INTERESTS OF THE *AMICI CURIAE*

Amici curiae are healthcare-focused unions and policy advocates, practicing physicians, academics, and researchers: some have served as medical consultants to pharmaceutical manufacturers, including to their marketing teams.[1] *Amici* have seen firsthand – both in a clinical setting and in consulting capacities – the harm that can occur when manufacturers violate the Food, Drug & Cosmetics Act ("FDCA") and False Claims Act ("FCA") by promoting their drugs for off-label uses that have not been approved by the Food & Drug Administration and that have often been unsafe or ineffective.

Amici have a strong interest in the questions presented in this case, which are fundamental to the scope of liability under the FCA. *Amici* believe the FCA has fostered evidence-based medicine, prevented patient harm, and facilitated recovery of billions of dollars for the government. *Amici* are united by a goal to preserve the FCA as an effective tool to combat improper off-label promotion and other fraudulent conduct that causes the government to pay money not lawfully owed.

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[1] *Amici* are National Nurses United – California Nurses Association ("NNU"), Dr. Aaron Kesselheim, Dr. Douglas Melnick, Dr. Stephen Fadem, and Dr. Aldebra Schroll. No counsel for a party authored any part of this brief, and no person other than *amici curiae* or their counsel made a monetary contribution for the brief's preparation or submission. All parties have consented to the filing of this brief.

For decades, violations of the FDCA and other regulations have served as predicates for liability under the FCA in cases where the violations are material and the defendant acts with scienter to divest the government of money it does not lawfully owe. Last year, the United States Supreme Court rejected invitations to overturn Congressional intent and limit FCA liability to situations in which a defendant makes express false statements during the process of submitting claims to the government. *See Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016). Appellant and *amici* supporting Appellant seek to relitigate *Escobar* and ask this Court to adopt interpretations that vitiate its holdings, holdings of other Supreme Court decisions, and this Court's existing precedent.

Amici agree that Appellees' interpretations are consistent with the mandates of *Escobar* and the Supreme Court's prior FCA decisions as well as this Court's existing precedent. *Amici* submit this brief because Appellant's contrary interpretations and the interpretations of *amici* such as the United States Chamber of Commerce have wide-ranging implications beyond the instant case and, if adopted, would gut the effectiveness of the False Claims Act as a tool to combat fraud.

SUMMARY OF THE ARGUMENT

The law is well settled that the FCA applies to all types of fraud, without qualification, that might result in financial loss to the federal government. Despite the contentions of Appellant and *amici* supporting it, the Supreme Court's ruling in

Escobar did not alter this fundamental precedent and clear Congressional intent. As the Supreme Court acknowledged, *Escobar* did not limit or modify FCA precedent, but instead was a narrow holding applied to a specific set of facts. *Escobar* only confirmed the viability of one specific theory of fraud (*i.e.*, a false claim predicated on violation of regulations under an implied certification theory), holding lower courts should find triable issues of FCA liability under this theory if certain conditions are satisfied. This construct was not designed to limit other theories that might be available, nor does the construct apply to all other theories of fraud available under the FCA. Accordingly, as the government recently argued in statements of interest, long standing theories of fraud—such as fraudulent inducement, promissory fraud, worthless services, and other types of fraudulent conduct—that are not predicated on the existence of specific representations made in a claim for payment, remain viable theories of fraud under the FCA.[2]

Escobar is entirely consistent with the Ninth Circuit's rulings in *United States ex rel. Campie v. Gilead Scis., Inc.*, 862 F.3d 890, 2017 U.S. App. LEXIS 12163 (9th Cir. July 7, 2017) ("*Campie*") and *United States ex rel. Hendow v. Univ. of Phx.*, 461 F.3d 1166 (9th Cir. 2006) ("*Hendow*"). The district court's ruling below also is consistent not only with *Escobar* but with the Ninth Circuit's long-standing

[2] *See, e.g.,* Statement of Interest of the United States at 9-10, *U.S. ex rel. Kolchinsky v. Moody's Corp.,* No. 12-cv-01399, (S.D.N.Y. May 08, 2017) (Dkt. 90).

precedent, and did not alter basic doctrines which existed pre-*Escobar* and still exist post-*Escobar*. In particular, the Supreme Court's identification of the two conditions in *Escobar* under which liability may be imposed merely provided one example of conditions under which an implied certification theory may be used to prove liability, but in no way was limited to those two conditions. *Escobar* did not hold that these conditions must apply to every FCA case. Critically, the district court below properly found that the fraud in this case was material under *Escobar*, and that *Escobar* in no way altered the test for materiality in the Ninth Circuit, which the cases relied upon by Appellant cannot and do not refute.

BACKGROUND ON HEALTHCARE FRAUD AND OFF-LABEL PROMOTION

Before addressing the specific Questions Presented in their legal argument section, *amici* briefly summarize the history of the FCA as a tool to address healthcare fraud and off-label promotion to highlight the impact the Court's decision in this case could have on FCA cases predicated on these violations.

In 1986, Congress strengthened the False Claims Act in response to evidence that government fraud – and healthcare fraud in particular – was "on a steady rise." S. Rep. No. 99-345, at 2 (1986), 1986 U.S.C.C.A.N. 5266, 5267. Congress found that the U.S. Department of Health and Human Services ("HHS") "ha[d] nearly tripled the number of entitlement program fraud cases referred for prosecution" between 1983 and 1986. *Id.* Nevertheless, the majority of such fraud went

undetected. *See id.* at 2-3, 1986 U.S.C.C.A.N. 5267-68. Congress sought to strengthen the FCA as "the Government's primary litigative tool for combatting fraud" and to "make the statute a more useful tool against fraud in modern times." *Id.* at 2, 1986 U.S.C.C.A.N. 5266.

In 2009, Congress declared the reinvigorated FCA "[o]ne of the most successful tools for combating waste and abuse in Government spending." S. Rep. No. 111-10, at 10 (2009), 2009 U.S.C.C.A.N. 430, 437. It enacted the Fraud Enforcement and Recovery Act of 2009, Pub. L. No. 111-21, 123 Stat. 1617, to "broaden the coverage" of the FCA against "fraud affecting . . . federal assistance and relief programs," S. Rep. No. 111-10, at 16, 2009 U.S.C.C.A.N. 442, by abrogating "several court decisions" that had "limited the reach of the False Claims Act," "derailed meritorious actions," and thus "jeopardiz[ed] billions in Federal funds," H.R. Rep. No. 111-97, at 2, 5 (2009); *see also* S. Rep. No. 111-10, at 10, 2009 U.S.C.C.A.N. 437-38.

Federal and state spending on healthcare programs continues to grow rapidly, driven by an aging population and rising healthcare costs. In 2015, Medicare expenditures totaled more than $646 billion, and Medicaid expenditures totaled $545.1 billion.[3] In 2016, pursuant to the False Claims Act, DOJ obtained over $2.5

[3] *See* https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/nhe-fact-sheet.html (last visited, August 6, 2017)

billion in settlements and judgments from civil cases involving fraud and false claims against federal healthcare programs; the FCA thus recovered the lion's share of the total $3.3 billion recovered as a result of healthcare fraud judgements, settlements, and administrative impositions.[4]

Notwithstanding Congress's bolstering of the FCA, healthcare fraud remains rampant.[5] A "staggering . . . 10 percent of the federal health care budget" is "lost to fraud" yearly.[6] Thus, even though the $2.5 billion recovered under the FCA involving healthcare fraud is impressive, and even under the broad interpretations the Supreme Court mandated in *United States v. Neifert-White Co.*, 390 U.S. 228 (1968) and reiterated in *Escobar* – interpretations Appellant assails – FCA cases have recouped only a tiny fraction of estimated losses.

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[4] *See* https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-01-18-2.html?DLPage=3&DLEntries=10&DLSort=0&DLSortDir=descending (last visited, August 6, 2017).

[5] *See* GAO Report to Congressional Committees, High-Risk Series: An Update 1, 342-84 (Feb. 2015), http://www.gao.gov/ assets/670/668415.pdf (last visited, August 6, 2017).

[6] Joan H. Krause, A Conceptual Model of Health Care Fraud Enforcement, 12 J.L. & Pol'y 55, 55 (2003); *see also* National Health Care Anti-Fraud Ass'n, Combating Health Care Fraud in a Post-Reform World: Seven Guiding Principles for Policymakers 3 (Oct. 6, 2010) (estimating $70-$234 billion in fraud losses), http://www.nhcaa.org/media/5994/whitepaper_oct10.pdf (last visited, August 6, 2017).

Off-label promotion is a type of healthcare fraud and refers to the improper marketing of drugs or medical devices for uses that are not approved by the FDA. *See, e.g., United States ex rel. Brown v. Celgene Corp.*, 226 F. Supp.3d 1032, 1038 n.3 (C.D. Cal. 2016). It is generally viewed as unlawful and a violation of the FDCA (*id.*), and the Centers for Medicare & Medicaid Services ("CMS") has issued guidance on its dangers, explaining that such promotion can cause "patient harm," cautioning that "[p]romoting off-label use that is not medically accepted may have a negative impact on quality of care," and expressly warning that such promotion may subject pharmaceutical manufacturers to liability under the False Claims Act.[7]

"Unlawful off-label drug promotion has been the subject of significant health care fraud enforcement efforts by the United States Department of Justice (DOJ) and the States' attorneys general using the Federal False Claims Act,"[8] and there have been at least 36 FCA settlements since 2004 predicated on off-label promotion, resulting in the recovery of billions of dollars to the federal government.[9] Despite

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[7] *See* Off-Label Pharmaceutical Marketing: How to Recognize and Report It, *available at* https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/Downloads/off-label-marketing-factsheet.pdf (last visited, August 6, 2017). *Amici* note that responses to unsolicited requests for information and off-label communications may be appropriate in certain limited circumstances, the discussion of which is beyond the scope of this brief.

[8] *Id.*

[9] *See* https://en.wikipedia.org/wiki/List_of_off-label_promotion_ pharmaceutical_ settlements (last visited, August 6, 2017).

suggestions by some that *Escobar* has changed or should change the legal landscape and suggestions that off-label promotion should enjoy constitutional protection,[10] FCA cases continue to settle for large sums to this day.

As recently as July 2017, an FCA case predicated on allegations of off-label promotion – the *Brown v. Celgene* case – settled for $280 million after summary judgment was denied.[11] As recently as July 7, 2017, this Court affirmed that misbranding – which can be caused by off-label promotion – can form the predicate for an FCA violation. *See generally Campie*, 862 F.3d 890.

ARGUMENT

I. *Escobar* Did Not Alter The Ninth Circuit's False Claims Act Jurisprudence

Decades ago, the United States Supreme Court instructed that the False Claims Act is to be construed broadly "to reach all types of fraud, without qualification, that might result in financial loss to the Government." *Neifert-White*,

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[10] In 2012, in a case considering whether a sales representative could face criminal penalties for off-label promotion, the Second Circuit held that a narrow type of "truthful" off-label promotion should fall under the First Amendment protection of commercial speech. *United States v. Caronia*, 703 F.3d 149, 160, 168 (2d Cir. 2012). The dissent (by Judge Debra Ann Livingston) in *Caronia* was fierce (*id.* at 169-182), no other appellate court has adopted the majority's holding, and the FDA has continued to resist attempts by pharmaceutical manufactures to undermine its rules restricting off-label communications. *See* https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM537130.pdf (last visited, August 6, 2017).

[11] https://www.justice.gov/usao-cdca/pr/celgene-agrees-pay-280-million-resolve-fraud-allegations-related-promotion-cancer-drugs (last visited, August 6, 2017).

390 U.S. at 232-33. This Court has repeatedly emphasized the same point. *See Campie*, 2017 U.S. App. LEXIS 12163, at *13-14 (same); *Hendow*, 461 F.3d at 1170 (same); *see also* S. Rep. No. 99-345, at 9 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266, 5274) (the FCA "reach[es] all fraudulent attempts to cause the Government to pay [out] sums of money or to deliver property or services").[12] "What matters is not the label the Government attaches to a requirement, but whether the defendant knowingly violated a requirement that the defendant knows is material to the Government's payment decision." *United States ex rel. Kelly v. Serco, Inc.*, 846 F.3d 325, 332 (9th Cir. 2017) (quoting *Escobar*, 136 S. Ct. at 1996).

This broad construction has "given rise to a number of doctrines 'that attach potential False Claims Act liability to claims for payment that are not explicitly and/or independently false.'" *Campie*, 2017 U.S. App. LEXIS 12163, at *14 (quoting *Hendow*, 461F.3d at 1171). *Escobar* addressed one such doctrine – the implied certification theory, a judicial construct developed in the first instance precisely because fraud can take many forms. *Escobar* considered one situation in which the defendant did not make express false statements during the claim submission process, but it did not overrule *Neifert-White* and did not purport to

[12] *See also United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 306 (3d Cir. 2011); U*nited States ex rel. Clausen v. Lab. Corp. of Am.*, 290 F.3d 1301, 1309 (11th Cir. 2002); *Harrison v. Westinghouse Savannah River, Co.*, 176 F.3d 776, 788 (4th Cir. 1999).

address all bases for FCA liability. On the contrary, the Court expressly qualified the scope of its decision, explaining that it (1) was clarifying only "*some* of the circumstances in which the False Claims Act imposes liability" and (2) was not deciding "whether all claims for payment implicitly represent that the billing party is legally entitled to payment." *Escobar*, 136 S. Ct. at 1995, 2000 (emphasis added).

Thus, as this Court recently reiterated, regardless of any label, "the four essential elements identified [in *Hendow*] remain the same." *Campie*, 2017 U.S. App. LEXIS 12163, at *21. Those elements are "(1) a false statement or fraudulent course of conduct, (2) made with the [sic] scienter, (3) that was material, causing (4) the government to pay out money or forfeit moneys due." *Id.* at *13 (quoting *Hendow*, 461 F.3d at 1174).

Using the *Neifert*/*Hendow* framework, the Ninth Circuit has repeatedly applied the FCA broadly to situations that do not involve "implied" certification or any certification whatsoever. For example, both *Hendow* and *Campie* recognized potential FCA liability for "promissory fraud" or "fraud in the inducement." *Campie*, 2017 U.S. App. LEXIS 12163, at *21 (quoting *Hendow*, 461 F.3d at 1173). "Under this theory, liability will attach to each claim submitted to the government under a contract, when the contract or extension of the government benefit was originally obtained through false statements or fraudulent conduct." *Id.*

Consistent with the Supreme Court's sweeping pronouncement regarding the FCA's broad reach in *Neifert-White*, fraudulent inducement has proven a viable legal theory in FCA cases with regard to a series of separate government agencies, and an array of different decisions (including in this Circuit): the Department of Defense contracting for the purchase of a product (*see In re Baycol Prods. Litig.*, 732 F.3d 869, 876 (8th Cir. 2013)); the Department of Education to obtain federal subsidies (*Hendow*); the Department of Energy for the award of a subcontract (*Harrison*, 176 F.3d at 791-94); and the FDA with regard to the approval of a drug (*Campie*).

Turning to the timing of the *Campie* case, it is critical to note that *Campie* was decided nearly a *year* after the Supreme Court issued its opinion in *Escobar*. That *Campie* reiterated the viability of the fraudulent inducement theory in the 9th Circuit post-*Escobar* strongly suggests that *Escobar* should not be read by this Court to have any effect on the law as originally outlined in *Hendow*.

Moreover, as noted, *Escobar* addressed the theory of implied false certification, a legal theory that operates independent of the fraudulent inducement theory. The *Campie* Court found that relator had adequately alleged promissory fraud because the defendant "committed either factually false or impliedly false certification through its representations to the FDA and labeling of its products, [thus] each claim was fraudulent even if false representations were not made therein." *Campie,* 2017 U.S. App. LEXIS 12163, at *28. Thus viewed, the *Campie*

decision cannot rationally be read as anything but a strong, post-*Escobar* endorsement of the fraudulent inducement theory in FCA actions, *i.e.*, *Hendow* remains the law in the 9th Circuit.

In *United States ex rel. Lee v. SmithKline Beecham, Inc.*, 245 F.3d 1048, 1053 (9th Cir. 2001), this Court held that a theory based on knowingly providing "worthless services" is "actionable" "regardless of any false certification conduct." Under this theory, although the product or services are delivered to the Government, they are so deficient that they are effectively worthless. "Neither false certification nor a showing of government reliance on false certification for payment need be proven if the fraud claim asserts fraud in the provision of goods and services." *Id.*

Campie differentiated worthless services from a theory of liability for "non-conforming goods," explaining that relator had stated a claim for non-conforming goods where the products paid for by the government did not meet FDA standards. *Campie*, 2017 U.S. App. LEXIS 12163, at *16; *see also United States v. Nat'l Wholesalers*, 236 F.2d 944, 950 (9th Cir. 1956); *Wilkins,* 659 F.3d 295 at 305. As the Court explained, the value of the goods at issue is immaterial to the claim. *Id.*; *see also United States v. Aerodex, Inc.*, 469 F.2d 1003, 1007-08 (5th Cir. 1972) ("The mere fact that the item supplied under contract is as good as the one contracted for does not relieve defendants of liability if it can be shown that they attempted to deceive the government agency.").

Significantly, although the *Campie* court identified non-conforming goods as a specie of "factually false certification," it explained that "a claim for nonconforming goods is not limited to situations where there is an express specification in a payment contract between a supplier and the government regarding the disputed aspect of the product to be supplied." *Campie*, 2017 U.S. App. LEXIS 12163, at *15-18. Indeed, this Court noted that *Escobar* eschewed such a "circumscribed view." *Id*. at *17.[13]

The *Neifert*/*Hendow* framework is optimal for many FCA cases for another reason. In *Escobar*, the entities committing fraud and submitting claims are one in the same. But a defendant that *causes* submission of a false claim may be liable under the FCA, regardless of whether that defendant is the one who actually submits the claim or makes any associated representation. *See, e.g.*, *United States ex rel. Hutcheson v. Blackstone Med., Inc*., 647 F.3d 377, 390 (1st Cir. 2011); *United States ex rel. Duxbury v. Ortho Biotech Prods., L.P*., 579 F.3d 13, 29-30 (1st Cir. 2009); *United States ex rel. Bergman v. Abbott Labs*., 995 F. Supp. 2d 357, 367 (E.D. Pa. 2014). Such third-party inducement is at the core of FCA cases involving a pharmaceutical company's off-label promotion, in which the company markets its

[13] Logically, this rationale applies with equal force to materially non-conforming services that violate core regulatory provisions authorizing (and limiting) government payment.

drugs for uses unapproved by the FDA. These uses are often ineffective or unsafe and their reimbursement is often prohibited by Medicare statutes.

As *Campie* recognized, such fraud on an agency can give rise to FCA liability. *Campie*, 2017 U.S. App. LEXIS 12163, at *24-25. Off-label promotion has been long recognized as a basis for FCA liability and actions on this principle have recouped billions of dollars for the United States, both before and after *Escobar*. *See, e.g.*, *Brown*, 226 F. Supp. 3d at 1052;14 *United States ex rel. Brown v. Pfizer*, No. 05-6795, 2016 U.S. Dist. LEXIS 25723 (E.D. Pa. Mar. 1, 2016); *United States ex rel. Cestra v. Cephalon, Inc*., No. 14-1842, 2015 U.S. Dist. LEXIS 71505 (E.D. Pa. June 3, 2015); *United States ex rel. Gohil v. Aventis, Inc*., No 02-2964 (E.D. Pa. Aug. 20, 2015) (Dkt. 151); *United States ex rel. Lisitza v. Johnson & Johnson*, 765 F. Supp. 2d 112 (D. Mass. 2011); *Strom ex rel. United States v. Scios, Inc*., 676 F. Supp. 2d 884 (N.D. Cal. 2009); *United States ex rel. Franklin v. Parke-Davis*, 147 F. Supp. 2d 39 (D. Mass. 2001); *see also United States ex rel. Gohil v. Aventis, Inc*., No 02-2964, 2017 U.S. Dist. LEXIS 3236 (E.D. Pa. Jan. 10, 2017) (denying judgment on the pleadings).

[14] The Celgene summary judgment decision post-dates *Escobar* by 6 months, and as noted above, the case settled for $280 million in July 2017, more than one year after *Escobar* was decided. As set forth more fully below, the district court in that case carefully considered the *Escobar* materiality standard and correctly rejected the narrow interpretation Appellant urges the Court to adopt in this case.

Escobar did not consider – and does not reach – the above situations. It addresses only the situation in which a defendant who submits claims directly to the government fails to disclose its noncompliance with a regulation, and such failure – if material – deprives the government from getting the benefit of the bargain for which it paid. Even with respect to that theory, rather than identifying conditions that are *necessary* for FCA liability, *Escobar* merely set forth conditions that are *sufficient* for FCA liability when they exist.[15] It expressly stated that it was not reaching any broader questions concerning the scope of FCA liability, and thus should not be construed as foreclosing other avenues of FCA liability.

In short, conduct in the *Rose* case and other conduct often at issue in FCA cases can and does constitute cognizable fraud independent of *Escobar*, which neither addressed nor undermined this Court's existing FCA jurisprudence or other bases for FCA liability.[16]

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[15] Requirements other than falsity and materiality – such as claim presentment and scienter – that were not before the Supreme Court would also need to be satisfied.

[16] Although *amici* have not analyzed the issue in depth, the conduct at issue in *Rose* likely supports FCA liability under doctrines other than implied false certification pursuant to this Court's decision in *Campie*. Just as the district court in *Campie* "did not have the benefit of *Escobar* in making its decision," prompting this Court's reversal in *Campie* (*see Campie*, 2017 U.S. App. LEXIS 12163, at *19), the district court in this case did not have the benefit of *Campie* when limiting its liability analysis to an implied false certification theory.

II. *Escobar*'s Two Conditions Should Not Be Required In Every Implied Certification Case

Amici are aware of this Court's recent statement in *Campie*, 2017 U.S. App. LEXIS 12163, at *20, indicating that *Escobar*'s two "conditions must be satisfied" for liability to attach under the implied certification theory, but as Appellees point out, that statement was *dicta*. *See* Appellees' Br. at 28-29 [Dkt. 24]. Respectfully, the question of whether the two conditions identified in *Escobar* must be satisfied in every implied certification case was not before the panel in *Campie* and was not briefed. The *Escobar* Court clearly stated that liability would lie under an implied certification theory "*at least*" when the two conditions it described are satisfied. *Id.* at 2001 (emphasis added).[17] Moreover, *Campie* itself recognizes that *Escobar* did not define the outer limits of implied certification, stating, "In *Escobar*, the Supreme Court recently 'clarif[ied] *some* of the circumstances in which the False Claims Act

[17] Appellant seeks to mislead the Court by flipping *Escobar*'s "at least" and "where," stating, "In *Escobar*, a unanimous Supreme Court affirmed that an implied certification can be the basis for liability under the FCA where 'at least' two conditions are established . . . ." Appellant's Br. at 12 [Dkt. 13] (quoting *Escobar*, 136 S. Ct. at 2001). *See also id.* at 17, 23-24. The Chamber of Commerce's *amicus* brief is similarly misleading: it ignores the Supreme Court's repeated use of the qualifying words "at least" in referring to the scope of the implied certification theory by simply leaving them out, stating that the Court "limit[ed] the reach of its implied certification decisions to cases where 'two conditions are satisfied . . . .'" Chamber Am. Br. at 5 [Dkt. 19] (quoting *Escobar*, 136 S. Ct. at 2001). As Appellees point out, the Supreme Court imposed no such limitations and none should be inferred. *See* Appellees' Br. at 24-25.

imposes liability' under this theory." *Campie*, 2017 U.S. App. LEXIS 12163, at *19 (emphasis added).

This Court should not construe *Escobar* or *Campie* to impose a mandatory requirement on every implied certification case. Not every such case will involve a specific representation about the goods or services provided that is rendered a half-truth. In some cases, the good or service may be provided as specified in the claim for payment, but the failure to disclose a violation renders the claim false nonetheless. For example, in a case involving off-label marketing, representations as to the goods and services provided may not be misleading or half-truths – a drug may be provided as stated.[18]

[18] Nonetheless, claims induced by off-label promotion may be cognizable under the conditions identified in *Escobar* – in addition to other theories – if the conduct renders *other* representations made in the claims submission process false or misleading. Such claims would be cognizable under *Escobar's* rubric when a defendant – by design – induces off-label uses that are statutorily ineligible for reimbursement. Although beyond the scope of this brief, Medicare Part D sponsors, physicians, and pharmacies submitting claims to Medicare make representations that they have complied with Medicare laws and that the drug uses at issue are eligible for reimbursement. Such representations are made in both the contracting and claims submission process. A manufacturer's knowing violation of the FDCA and promotion of off-label drug uses that are ineligible for reimbursement make such representations false and misleading because: (1) Medicare laws were violated; and (2) the induced uses are not covered by Medicare and are not eligible for reimbursement. *Amici* can attest that pharmaceutical manufacturers have often misrepresented the nature of off-label uses, deceiving physicians by promoting such uses as safe, effective, and reimbursable even when they are none of these things.

Claims for payment – like in *Rose* – will often be half-truths precisely because of the materiality of the regulatory or contractual violations at issue and irrespective of any specific misrepresentations. Knowing violations of the incentive compensation ban ("ICB") constitute a fraudulent course of conduct directed at divesting money from the government by submitting claims that would not have existed at all but for the violations of the ICB. Such conduct becomes an FCA violation when the school submits a claim to receive money to which it is not lawfully entitled, *i.e.*, a claim that is statutorily ineligible for reimbursement and thus false. *Ebeid ex rel. United States v. Lungwitz*, 616 F.3d 993, 1001 (9th Cir. 2010).

Nevertheless, if this Court determines that *Escobar's* two conditions must be satisfied for an implied certification FCA case, it should, as it did in *Campie*, construe the requirement loosely. There, the Court held that the products' names were the requisite "specific representations" because "these drug names necessarily refer to specific drugs under the FDA's regulatory regime" (*i.e.*, the names implied they were "medications approved by the FDA that were manufactured at approved facilities and were not adulterated or misbranded.") *Campie*, 2017 U.S. App. LEXIS 12163, at *23. Further, defendant "requested payment for drugs that fell outside of that approval and omitted critical information regarding compliance with FDA standards," thus making the representations – the product names – misleading half-truths. *Id*. at *23-24.

In this case, the very act of submitting a request for Title IV funds necessarily implies eligibility for those funds. Further, AAU represented in its claims for payment that it was issuing funds to an eligible student enrolled in an eligible program. *See* ER9. [19] AAU's claims for payment were misleading half-truths because, as the district court already found, AAU's noncompliance with the ICB violated the terms of its plan participation agreements, making it ineligible for Title IV funding. *See id*.; *see also Ebeid*, 616 F.3d at 998 ("Implied false certification occurs when an entity has previously undertaken to expressly comply with a law, rule, or regulation, and that obligation is implicated by submitting a claim for payment even though a certification of compliance is not required in the process of submitting the claim.").

AAU counters that its representation about eligibility refers only to *institutional* eligibility, which is not subject to the ICB ban and so was never in jeopardy. Appellant Br. at 28-35. Therefore, AAU asserts that the claims submitted did not contain any false representations. *Id*. at 35. This is irrelevant. *Escobar* does not require an affirmative false statement. Rather, the specific representation may simply be a misleading half-truth. To hold that a school's specific representations were not a misleading half-truth just because the school retained its institutional

[19] "ER" refers to Appellant's Excerpts of Record.

eligibility, despite not being eligible for the very funds it was seeking, would elevate form over substance and undercut the government's ability to combat fraud.[20]

The Chamber of Commerce, however, urges this Court to apply *Escobar*'s conditions strictly to every implied certification case, citing a string of cases for the proposition that absent such strict enforcement, FCA liability will be imposed for minor regulatory or contractual infringements. Chamber Am. Br. at 11-15. But the Supreme Court has made it clear that rigorous application of the FCA's *materiality* requirement will prevent liability for minor violations. *See Escobar*, 136 S. Ct. at 2002.

Escobar reasoned that "concerns about fair notice and open-ended liability 'can be effectively addressed through strict enforcement of the Act's materiality and scienter requirements,'" which "are rigorous." *Id.*; *see also Campie*, 2017 U.S. App. LEXIS 12163, at *14 n.4 (noting that *Escobar* did not reject the court's "obligation to construe broadly any theory of liability in which materiality can be proven").

[20] Notably, the Department of Education recently disallowed funding for Charlotte School of Law for engaging in fraudulent practices. The Department did not order the school to *close* but cut its access to federal loan dollars.

III. Appellees' Interpretations of Materiality Requirements Properly Limit The Scope Of The FCA

Although *amici* do not seek to reargue all points Appellees made regarding materiality, *amici* believe several additional points will be instructive for the Court.

A. Materiality requirements have long resulted in dismissal of frivolous cases

Even before *Escobar*, courts applied a materiality requirement to weed out frivolous cases. In *Wilkins*, one example cited by the Chamber of Commerce, the Third Circuit adopted the implied certification theory but upheld the district court's dismissal of marketing claims, concluding that the violations alleged by the relator were not relevant to the government's decision to pay the defendant insurance companies. *Wilkins*, 659 F.3d at 309. *See also id*. ("Since the Act is restitutionary and aimed at retrieving ill-begotten funds, it would be anomalous to find liability when the alleged noncompliance would not have influenced the government's decision to pay.") (quoting *Mikes v. Straus*, 274 F.3d 687, 696 (2d Cir. 2001)).

Notably, each of the cases cited by the Chamber of Commerce in its "parade of horribles" was dismissed *without* a strict application of *Escobar*'s two-part test and without interpreting materiality as Appellant and the Chamber urge. *See United States ex rel. McBride v. Halliburton Co*., 848 F.3d 1027, 1028 (D.C. Cir. 2017) ("McBride failed to offer evidence that any misrepresentation regarding headcount data (if one existed) was material to the Government's decision to pay."); *United*

States ex rel. McLain v. Kellogg Brown & Root Servs., Inc., No. 1:08-CV-499, 2014 U.S. Dist. LEXIS 92072 (E.D. Va. July 7, 2014) ("the Amended Complaint fails to plausibly state a claim because the materiality of the false logs, reports, and certifications is inadequately pled"), *aff'd per curiam*, No. 14-1816, 2015 U.S. Dist. LEXIS 14207 (4th Cir. Aug. 13, 2015).[21]

Although it post-dates the *Escobar* decision, *Kelly v. Serco, Inc.* was also primarily resolved on the basis of materiality. This Court upheld summary judgment against the relator on implied certification, in part, on the basis of *Escobar's* two conditions, but largely because the violation at issue was not material to the government's decision to pay. 846 F.3d at 332-33. It is readily distinguishable factually from this case. First, there was no evidence of any express or implied false or fraudulent statement. *See Kelly*, 846 F.3d at 333. Second, the regulation at issue, a regulation governing the *format* of cost reports, did not independently bind defense contractors absent incorporation into the contract governing the relationship with the Department of Defense (DoD). *Id.* at 330-31. In *Kelly*, it was *not* a condition of the

[21] The remaining FCA cases the Chamber cites also were readily dismissed by the courts, albeit not on materiality grounds. *See United States ex rel. Rostholder v. Omnicare, Inc.*, No. 07-cv-1283, 2012 WL 3399789, at *48-49, 52 (D. Md. Aug. 14, 2012); *United States ex rel. Quinn v. Omnicare Inc.*, 382 F.3d 432, 440, 446-47 (3d Cir. 2004). *Carmichael v. Kellogg, Brown & Root Servs., Inc.* was not an FCA case at all, but it nonetheless was dismissed because the alleged regulatory violations raised political questions inappropriate for the court to resolve. 572 F.3d 1271, 1275 (11th Cir. 2009).

contract, which instead *specified* production in the form defendant delivered. *Id.* at 331.

But most importantly, the purported violation was not material because DoD contacts had expressly, *prospectively*, and repeatedly approved the non-compliant reporting methods used by the contractor. *Id.* at 331, 334. Notably, it ultimately decided to discontinue receipt of the reports because it did not find them useful. *Id.* at 334.

In the face of overwhelming evidence that the government received (and paid for) cost reports in the precise format it wanted and contracted for – until discontinuing their production entirely – relator offered a conclusory statement that the contracting agency would not have paid the vouchers if it knew Serco's reports did not comply with regulation. *See Kelly*, 846 F.3d at 333-34. In the absence of *any* evidence of materiality beyond the arguable ability "to refuse payment were it aware of the violation," which *Escobar* deemed "insufficient by itself to support a finding that the violation is material to the government's payment decision," this Court found lack of materiality as a matter of law. *Id.* at 334. [22]

[22] It is doubtful there was ***any*** violation in *Kelly* in the first instance as the regulation did not bind defense contractors absent the DoD contracting officer incorporating it into the contract at issue. *E.g.*, 48 C.F.R. §§ 34.203(c), 52.234-4(a); 48 C.F.R. §§ 234.203(2), 252.234-7002(b)(1); 48 C.F.R. § 2.101 (Definitions generally); 48 C.F.R. § 2.101(b)(2). In *Kelly*, the contracting officer had not.

Kelly is not remotely similar to the *Rose* case or virtually any other case. In other recent cases, this Court has found that relators state claims under the FCA when defendant's alleged violations are plausibly material, regardless of the absence of any specific representation in the claim for payment. *E.g.*, *Campie*, 2017 U.S. App. LEXIS 12163, at *39. Contrary to the suggestions of Appellant and the Chamber, no cases support an argument that *any* continued payment following allegations of FCA violations equates to payment with "actual knowledge" of violations sufficient to establish non-materiality as a matter of law.

B. The District Court Properly Applied *Escobar's* Materiality Standard in Its Alternative Holding

Appellees correctly state that the district court's fact-intensive alternative holding that the ICB is material under *Escobar* need not be addressed on appeal. Appellees' Br. at 50-51. Indeed, this Court and other appellate courts have dismissed interlocutory appeals – or portions thereof – as improvidently granted where they do not implicate pure questions of law and instead require extensive factual analysis. *See, e.g., Wood v. GCC Bend, LLC*, 422 F.3d 873, 880-81, 883 (9th Cir. 2005); *United States ex rel. Michaels v. Agape Senior Cmty.*, 848 F.3d 330, 339-41 (4th Cir. 2017) (dismissing the issue of whether FCA liability or damages can be proven through statistical sampling as "improvidently granted," because it is not a "pure question of law" that the court could decide "quickly and cleanly"). But if this Court

chooses to analyze the alternative holding, *amici* respectfully submit that it should conclude the district court applied *Escobar* correctly.

Amici do not rebrief all arguments made by Appellees but highlight and reiterate a few key points.

As a threshold issue, the district court was correct in distinguishing between mere awareness of allegations of fraud and actual knowledge of fraud. *See* ER10-11. Under *Escobar*, only the latter is relevant to materiality. *See Escobar*, 136 S. Ct. at 2004. This distinction is important because allegations of fraud may be unproven, require investigation and be actively disputed by the defendant. Indeed, the "mere suspicion of wrongdoing" is not enough to impute actual knowledge of the fraud. *United States v. Pub. Warehousing Co. K.S.C.*, No. 1:05-CV-2968-TWT, 2017 WL 1021745, at *6 (N.D. Ga. Mar. 16, 2017). The First Circuit's decision on remand from *Escobar* also strongly supports this point. *See United States ex rel. Escobar v. Universal Health Servs.*, 842 F.3d 103, 112 (1st Cir. 2016) ("*Escobar II*") (holding "mere awareness of allegations [of misconduct] is different from [actual] knowledge," and discounting purported evidence that the Medicaid program had actual knowledge of the violation when it paid the claim).

Authority from this Court and district courts in this Circuit likewise support an argument that the "actual knowledge" element should be narrowly construed when analyzing the materiality of a violation. For example, in *Campie*, this Court

held there was insufficient evidence that the government had actual knowledge of the fraud when it paid claims for the defendant's drugs because "the parties dispute exactly what the government knew and when." 2017 U.S. App. LEXIS 12163, at *33-34. Thus, defendant had failed to establish conclusively that the government's continued payments were made with "actual knowledge" that defendant's drugs were adulterated and noncompliant. *Id.* at *32-34.

The *Campie* Court also noted that because the defendant stopped using unapproved and contaminated drugs, the government's decision to keep paying for compliant drugs "does not have the same significance" for materiality as it would if the government continued to pay despite continued noncompliance. *Id.* at *33. Similarly, evidence that Appellant began to comply with the ICB in this case would largely negate any basis to find non-materiality.

In denying summary judgment in the *Brown* case, Judge King of the Central District of California applied *Escobar* and made a factual determination after considering "five lines of evidence" that "[defendant] Celgene point[ed] to," holding that "[t]his evidence [was] insufficient to show that CMS 'regularly pa[id]' claims for off-label uses of Thalomid and Revlimid 'despite actual knowledge' that these uses were not medically accepted." *Brown,* 226 F. Supp. 3d at 1049-50 (internal quotations omitted); *see also United States ex rel. Duffy v. Lawrence Mem'l Hosp.*, No. 14-2256, 2017 U.S. Dist. LEXIS 105002, at *20 (D. Kan. July 7, 2017) (denying

motion for summary judgment and rejecting defendant's arguments on lack of materiality because "the strength of the evidence [of payment with actual knowledge of violations] submitted by [defendant] is subject to some reasonable dispute and, upon the current record, it is insufficient to extinguish an issue of fact").

When payments are made, absent unimpeachable evidence, it should be left to the trier of fact to determine whether they were made with "actual knowledge" of violations.

Finally, the district court was correct in concluding that "[n]othing in *Escobar* suggests that [governmental] actions short of a complete revocation of funds are irrelevant to the court's materiality analysis." ER12. Indeed, *Escobar* does not hold that a government agency must always revoke funds, terminate program participation, or immediately seek to recoup previously paid funds based on the alleged violation to establish the violation's materiality. Rather, the government has broad discretion to "choose among a variety of remedies, both statutory and administrative, to combat fraud." *United States ex rel. Onnen v. Sioux Falls Indep. Sch. Dist.*, 688 F.3d 410, 414-15 (8th Cir. 2012).

So long as the likely or actual effect of the violation would be revocation of a claim for payment, materiality can be established. *Escobar*, 136 S. Ct. at 2002*; see also Campie*, 2017 U.S. App. LEXIS 12163, at *34 (statutes regulating misbranded and adulterated drugs, including criminal statutes, demonstrate that misbranding

violations carry significant ramifications beyond FDA enforcement actions and may be sufficiently important to payment); *Miller v. Weston Educ., Inc.*, 840 F.3d 494, 504 (8th Cir. 2016) (government's prior enforcement efforts against educational institutions for violations of Title IV's recordkeeping requirements demonstrates the importance of these requirements for payment). As a practical matter, the reasoning in these decisions makes perfect sense. There are many reasons – including harm to third parties – why the government may choose not to cease all payment or cut all funding to FCA violators. This holds particularly true if a defendant *begins* to comply in response to a government investigation precipitated by and FCA case.

Applying this law to the instant case, there is a compelling basis to conclude that Appellant's violations of ICB are material. The Government has recovered more than $59 million for violations of the ICB. *See* ER11. Nor, as Appellant asserts, has the government clearly paid claims with actual knowledge that they violated the ICB. All claims subsequent to the investigation and settlements with the government were premised on the Title IV recipient changing its practices and complying with the ICB going forward. *See* Appellees' Br. at 52-55. Thus, DOE rightfully expected its subsequent payments to be for compliant claims. *Campie*, 2017 U.S. App. LEXIS 12163, at *32-33.

CONCLUSION

For these reasons, and those set forth in the appellees' brief, the judgment below should be affirmed.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I certify that this brief contains 6,852 words, and was written in Times New Roman with 14 pt. typeface, double-spaced, in compliance with Fed. R. App. P. 32.

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CERTIFICATE OF SERVICE

I hereby certify that on August 7, 2017, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system.

I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

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