UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: PLAVIX MARKETING, SALES PRACTICE AND PRODUCTS LIABILITY LITIGATION (NO. II)	MDL No. 2418
UNITED STATES OF AMERICA, *ex rel.* JKJ PARTNERSHIP 2011, *et al.*, *Plaintiff,* v. SANOFI-AVENTIS U.S. LLC, *et al.*, *Defendants.*	Honorable Freda L. Wolfson *Civil Action No.* 11-6476 (FLW)

UNITED STATES' STATEMENT OF INTEREST
REGARDING DEFENDANTS' MOTION TO DISMISS

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INTRODUCTION

The United States respectfully submits this statement of interest under 28 U.S.C. § 517 in response to Defendants' Renewed Motion to Dismiss Relator's Second Amended Complaint. Specifically, the Government submits this statement to address several arguments made by Defendants relating to the False Claims Act's falsity, materiality, and knowledge requirements. The False Claims Act ("FCA"), 31 U.S.C. §§ 3729–33, is the Government's primary tool to combat fraud and recover losses due to fraud in federal programs. The Government therefore has a substantial interest in how decisions regarding the FCA's requirements may shape enforcement under the statute.

Defendants' primary arguments are based on the mistaken premise that a prescription for a use of a drug that is approved by the Food and Drug Administration ("FDA") must be reimbursed by Medicare Part D as well as Medicaid, notwithstanding Defendants' alleged misrepresentations as to its efficacy. And so, they argue, that Relator has failed to plead falsity and materiality. But this argument ignores other requirements for reimbursement, namely that the prescription be medically necessary and reasonable for the particular patient. Relator has alleged that those requirements — which, if proven, may form the basis for FCA liability — were not met here.

Defendants next raise the argument that materiality cannot be satisfied where the Government has continued to reimburse for the drug notwithstanding knowledge of the allegations in the complaint. But this argument misstates the standard for Government knowledge as a defense to materiality. With respect to materiality, what matters is whether the Government has continued to pay despite ***actual*** knowledge of ***specific*** false claims. At most, the pleadings reflect that the alleged misrepresentations may have been brought to the attention of the federal agency responsible for making the payment. But these pleadings do not allege that this agency knew of

specific claims that that were false and paid those claims notwithstanding such actual knowledge. In addition, the agency may have continued payment for the drug at issue here for many reasons, including that it may be difficult to identify the false claims, or that it was unable to conclude based on the facts in front of it at the time of payment that those claims were false.[1]

Defendants also argue that the Government's decision not to intervene here is evidence of a lack on materiality. Wrong. The Government's decision whether to intervene (or not) in a *qui tam* action has no bearing one way of the other on materiality. The intervention decision can be based on a host of reasons unrelated to materiality and the FCA does not place a *qui tam* relater on unequal footing when litigating the case on behalf of the Government in a declined case.

Finally, Defendants argue that the scientific disagreement over efficacy negates knowledge for FCA purposes. But the alleged false statements in this case are not predicated upon the precise scientific explanation for the alleged diminished efficacy of the drug in question. Instead, Relator alleges that Defendants knew of the diminished efficacy but said the opposite: a lie, pure and simple.

BACKGROUND

A. The False Claims Act

The FCA is "the Government's primary litigative tool" for combatting fraud; it was intended "to reach all fraudulent attempts to cause the Government to pay out sums of money." S. Rep. No. 99-345, at 2, 9 (1986). Congress therefore drafted the statute "expansively . . . 'to reach all types of fraud, without qualification, that might result in financial loss to the Government.'"

[1] Indeed, under Part D of the Medicare Program, the federal agency which administers that program, the Center for Medicaid and Medicare Services ("CMS") pays insurance companies (called "Sponsors") monthly capitated payments. *See* 42 C.F.R. § 423.315(b). Those payments are determined in advance and it is the insurance companies that directly pay for the drugs prescribed to the Medicare beneficiaries that elect to be in the insurers' Part D plans. The same is true for the payment of drugs under various State Medicaid Programs.

Cook Cnty. v. United States ex rel. Chandler, 538 U.S. 119, 129 (2003) (citation omitted).

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 violation also occurs when a person "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." *Id.* § 3729(a)(1)(B).[2] The FCA authorizes suits to collect statutory damages and penalties either by the Government or by a private person (a *qui tam* relator) in the name of the United States. 31 U.S.C. § 3730(a), (b)(1); *see also Vermont Agency of Nat. Res. v. United States ex rel. Stevens*, 529 U.S. 765, 769–78 (2000). If a relator files a *qui tam* action, the Government may intervene and take over the case. 31 U.S.C. § 3730(b)(2). If the Government declines to intervene, the relator conducts the litigation. *Id.* § 3730(c)(3). A relator may be entitled to an award from a recovery in a *qui tam* action. *Id.* § 3730(d).

B. The Present Litigation

The Defendants marketed Plavix, a prescription drug approved by the FDA for acute coronary syndrome and certain other cardiovascular indications. The Relator generally alleges that the Defendants caused false claims to be submitted to federal healthcare programs by marketing Plavix without disclosing that it had no demonstrable effect for certain patients, which the Relator calls "non-responders." Specifically, the Relator alleges that roughly 30 percent of patients carry a genetic variant of a liver enzyme that causes a reduced response to Plavix (the Defendants refer

[2] The current version of these provisions took effect on May 20, 2009, after passage of the Fraud Enforcement and Recovery Act of 2009, Pub. L. No. 111-21, § 4, 123 Stat. 1617, 1621–25. The prior version had some differences in wording. *See* 31 U.S.C. § 3729(a)(1) (2006) (creating liability for any person who "knowingly presents, or causes to be presented" to a federal employee or official "a false or fraudulent claim for payment or approval"); *id.* § 3729(a)(2) (creating liability for any person who "knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government"). These wording differences, however, do not bear upon the present motion.

to this problem as the "Variability of Response" ("VOR") issue). Relator alleges that notwithstanding Defendants' knowledge that 30 percent of patients were non-responders, Defendants promoted Plavix as being effective for all patients.

The Government declined to intervene, and the Relator is litigating the action.

ARGUMENT

A prescription for an on-label use of a drug can still be the basis of a FCA claim if other payment conditions of the government program are not satisfied. As relevant here, if a prescription is not medically reasonable or necessary, as Relator has alleged is true for the 30 percent of patients who were "non-responders," then that claim does not comply with a payment condition. The agency's — here, CMS's — continued payment for Plavix, despite its purported general knowledge of the VOR issue, does not imply that medical necessity as to a particular claim is not material to CMS's payment of that particular claim. Put differently, the test for materiality is what the agency would have done if it had actual knowledge that Plavix was not effective for a particular beneficiary for whom a particular claim was submitted. Plainly the agency's purported inaction to date does not necessarily imply that it would not deny a claim in that scenario. Finally, Defendants are wrong both that a difference in scientific or medical opinion cannot form the basis for scienter under the FCA. Relator has not alleged a mere difference in scientific or medical opinion.

I. THE FALSE CLAIMS ACT'S FALSITY AND MATERIALITY REQUIREMENTS CAN BE SATISFIED WHEN A PRESCRIPTION IS FOR A USE THAT HAS BEEN APPROVED BY FDA

Defendants' argument (Mem. at 2 & 19), that the Government must pay for on-label uses of a drug (or other medical item or service) that are medically unnecessary or unreasonable (or unsafe or ineffective) for a particular patient is wrong and should be rejected by this Court. A drug prescription is not *per se* or even presumptively "reasonable and necessary" simply because it was

prescribed for an FDA-approved indication. *See United States ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481, 487–89 (3d Cir. 2017)). In *Petratos*, the Third Circuit rejected the argument that FDA approval of the drug necessarily meant that an on-label claim for the drug was "reasonable and necessary." *Id.* As the Third Circuit explained, "the 'reasonable and necessary' determination is a process involving the FDA, CMS, *and* individual doctors." *Id.* at 487. Accordingly, such a claim could be false if an individual doctor prescribed a drug in circumstances that were not reasonable and necessary. *Id.* at 489 (using as an example the provision of a chemotherapy drug to a patient who had no chance of recovery). So too here; the provision of Plavix under circumstances for a particular patient that were not medically "reasonable and necessary" could constitute a false claim.

Defendants also argue in a footnote (Mem. at 24 n.19) that *Petratos*' analysis regarding falsity and medical necessity is "inapplicable" to Medicare Part D claims because the decision concerned Medicare Part A and B claims. Not so. Medicare Part D has several differences from Medicare Part B, but on this point (unsurprisingly) they are the same: claims must be medically reasonable and necessary. The Medicare Part D statute expressly incorporates the "reasonable and necessary" requirement of Medicare Part B set forth in 42 U.S.C. § 1395y(a). *See* 42 U.S.C. § 1395w-102(e)(3)(A). The "reasonable and necessary" requirement is a fundamental, material requirement for each claim for payment under government healthcare programs, and accordingly a particular claim may be legally false if the use of a drug is not reasonable and necessary for a particular patient. *Id.* This requirement does not depend on whether the use is approved by the FDA. Notably, this argument has already been appropriately rejected in an opinion by another Judge in this district. *See United States ex rel. Penelow v. Johnson & Johnson*, Civ. No. 12-7758, 2017 WL 2367050, at *5 (D.N.J. May 31, 2017) (extending *Petratos* analysis to Medicare Part D).

Finally, this statutory provision also expressly states that a Medicare Part D insurer may exclude coverage if a claim for a drug does not meet the "reasonable and necessary" requirement for treatment of an illness. 42 U.S.C. § 1395w-102(e)(3)(A). Defendants' argument (Mem. at 18) that CMS or a Part D insurer "presumptively ***must*** reimburse for the on-label Plavix prescriptions at issue here" is belied by the statute itself. For this reason, Defendants' reliance on this Court's decision in *Dickson IV* is also misplaced. (Mem. at 18–19 (citing *In re Plavix Mktg., Sales Prac. & Prod. Liab. Litig. (No. II) ("Dickson IV")*, 332 F. Supp. 3d 927, 947 (D.N.J. 2017)).) The pleadings at issue in that decision established that the program at issue had no authority to deny on-label claims for Plavix. *Id.* at 947 ("Relator concedes that Plavix was listed on each state's PDL and that a PDL-listing alone was sufficient to compel government Medicaid payors *automatically* to reimburse claims for Plavix."). Accordingly, such a false claim can also satisfy the materiality element of the FCA.

For these reasons, this Court should reject Defendants' arguments that a claim for payment for an on-label use of a drug cannot be false even if the drug was prescribed to a patient for whom the drug was unreasonable or unnecessary. The United States, however, expresses no opinion in this brief about whether the claims for payment of Plavix for patients whom were alleged non-responders were unreasonable or unnecessary.

II. THE CONTINUED PAYMENT FOR A DRUG (OR DEVICE OR SERVICE) IS NOT DISPOSITIVE ON THE ISSUE OF WHETHER THE ALLEGED FALSITY WAS MATERIAL

The fact that a government agency continued to pay for a drug (or device or service) after allegations of false claims have been raised is not dispositive as to the FCA's materiality requirement. The FCA defines the term "material" as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4). The Supreme Court in *Escobar* explained that "materiality 'look[s] to the effect on the likely or

actual behavior of the recipient of the alleged misrepresentation.' " *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 2002, 195 L. Ed. 2d 348 (2016). The Supreme Court also made clear that "materiality cannot rest on a single fact or occurrence as always determinative." *Id.* at 2001 (citation omitted).

Defendants argue that a series of disclosures related to the alleged false claims mean that Relator has not pleaded materiality (Mem. at 20). Specifically, they argue that FDA learned of the non-responders issue in 2009, changed the label three times in response, and this case raised the alleged FCA violations in 2011, but CMS has continued to pay for Plavix to the present. The Supreme Court's discussion of the materiality standard in *Escobar* itself, however, makes clear that these disclosures do not foreclose a finding of materiality here. The Supreme Court recognized that evidence that "the Government pays a particular claim in full despite its ***actual*** knowledge that certain requirements were violated" is not dispositive with respect to materiality. *See Escobar*, 136 S. Ct. at 2003–04 (stating only that this showing would constitute "strong evidence" that a violation is not material) (emphasis added); *see also Petratos*, 855 F.3d at 490 (citing *Escobar* and using term "full knowledge."). And here, Defendants do not argue that the pleadings establish that the Government had ***actual*** knowledge of a violation of the "reasonable and necessary" requirement, i.e., that a specific patient had been prescribed Plavix despite being one of the alleged 30% of patients who were non-responders.

In addition, although the government agency's actual knowledge of a specific false claim can be relevant to the False Claims Act's materiality requirement, this type of evidentiary inquiry is normally not appropriate on a motion to dismiss, where the sole question is whether the complaint plausibly alleges a statutory violation. Absent an opportunity for discovery, it is unreasonable to expect or require detailed allegations from a relator concerning the government

agency's "actual knowledge" and the resulting pattern of action (or inaction) in response to such actual knowledge. This is particularly true where the issue is not simply whether the agency knew about potential medical concerns about a drug, but also whether it knew about the specific instances of the unreasonable use of the drug. *See, e.g.*, *United States ex rel. Escobar v. Universal Health Servs.*, 842 F.3d 103, 112 (1st Cir. 2016) ("We see no reason to require Relators at the Motion to Dismiss phase to learn, and then to allege, the government's payment practices for [analogous violations] in order to establish the government's views on the materiality of the violation. Indeed, given applicable federal and state privacy regulations in the healthcare industry, it is highly questionable whether Relators could have even accessed such information.").

Materiality also does not require that the agency stop paying for a drug (or other medical item or service) when there is an issue with some unidentified claims for some unidentified patients. If CMS had stopped paying for Plavix altogether it would have penalized the patients for whom the drug was reasonable and necessary. Nothing in *Escobar* suggests that government agencies must immediately stop all payments in order to establish that certain types of violations are material to payment. *See* 136 S. Ct. at 2003–04. And nowhere is this truer than with health care. CMS is the federal agency charged with ensuring the delivery of and payment for health care, including pharmaceutical drugs, to tens of millions of Americans enrolled in Medicaid and Medicare. Requiring it to stop all payments for a drug because it is unreasonably or unnecessary for some unidentified beneficiaries would be detrimental to other beneficiaries for whom the drug is reasonable and necessary. Also, while warnings about the use of a drug by the FDA might have some relevancy, the fact that a drug or use remains approved cannot be singly determinative. If the drug is still safe and effective for some patients, the FDA need not remove the drug from the market entirely. While there are circumstances in which the Government may properly halt

payments in the face of fraudulent conduct, such decisions are necessarily tempered by the need to ensure adequate access to health care.

What remains are simply CMS' purported awareness of Relator's allegations, which several courts have said are insufficient to defeat materiality. *See, e.g.*, *Escobar*, 842 F.3d at 112 (observing on remand from the Supreme Court that "mere awareness of allegations concerning noncompliance with regulations is different from knowledge of actual noncompliance"); *Smith v. Carolina Med. Ctr.*, 274 F. Supp. 3d 300, 325 (E.D. Pa. 2017) ("Actual knowledge is different from a strong suspicion that the claims were fraudulent."); *Silbersher v. Allergan Inc.*, No. 18-CV-03018-JCS, 2020 WL 7319407, at *41 n.22 (N.D. Cal. Dec. 11, 2020), *motion to certify appeal granted*, No. 18-CV-03018-JCS, 2021 WL 292244 (N.D. Cal. Jan. 28, 2021) ("Although the Government is on notice of Relator's *allegations* its continued payment for these drugs could be for any number of reasons."). Therefore, the fact that a government agency may continue to pay even after being made aware of allegations of wrongdoing does not establish a lack of materiality. The Court should make clear that allegations that an agency continued to pay claims are not dispositive at the pleading stage on the issue of whether the alleged falsity was material. Moreover, to the extent these allegations are relevant at all, they are relevant only where the agency had actual knowledge of the specific false claims (here, the claims for payment for the use of Plavix to treat patients who were non-responders) and paid those claims.

In sum, the Court's resolution of the materiality issue should reflect the fact that government payment decisions are not dispositive at the pleading stage. If these decisions are relevant at all at the pleading stage, they are relevant only where the complaint alleges that the government agency had actual knowledge of the specific claims that were false (*e.g.*, for the unreasonable use of a drug) and paid those claims. As demonstrated above, however, this relevancy

is not dispositive of materiality — all facts and circumstances relating to materiality still must be examined.

III. THE DEPARTMENT OF JUSTICE'S NONINTERVENTION IN THIS *QUI TAM* ACTION IS IRRELEVANT TO THE MATERIALITY INQUIRY

Defendants incorrectly suggest that the Department of Justice's decision not to intervene in this *qui tam* action is evidence of immateriality under the False Claims Act. (Mem. at 20–21.) That decision does not give rise to any inferences regarding the materiality of the alleged false statements or false claims. The FCA defines the term "material" as a falsity that has a tendency to influence "the payment or receipt of money." The Department of Justice is not the government agency that is the payor in most *qui tam* actions. In actions such as this one involving Medicaid and Medicare fraud, CMS was the government payor. Accordingly, the materiality inquiry must focus on CMS's payment for Plavix and not on the Department of Justice's intervention decision.

Significantly, the Supreme Court in *Escobar* understood the correct focus. That was a declined case, but the Supreme Court did not mention the Department of Justice's declination decision as a factor in its materiality analysis. Nor did the First Circuit, on remand, consider the declination as relevant to the materiality inquiry. *United States ex rel. Escobar v. Universal Health Servs., Inc.*, 842 F.3d 103, 112 (1st Cir. 2016); *see also United States ex rel. Prather v. Brookdale Senior Living Comtys., Inc.*, 892 F.3d 822, 836 (6th Cir. 2018) (adopting this reasoning). If the Department of Justice's decision not to intervene in a particular *qui tam* action was tantamount to a conclusion that the falsity was immaterial to the government agency's payment decision, there would have been no need for the Supreme Court to include an extensive discussion in its opinion about the factors that bear on materiality under the False Claims Act or for the First Circuit on remand to consider those other factors.[3]

[3] For this reason, the handful of district court opinions within the Third Circuit that have stated

In addition, the statutory scheme set forth by Congress provides relators the right to conduct an action if the Department of Justice declines. Treating a declination decision as evidence against a False Claims Act action litigated by relators would undermine the statutory scheme set forth by Congress. *See* 31 U.S.C. § 3730(b)(1), (c)(3), (d); *see also Prather*, 892 F.3d at 836 ("[T]he False Claims Act is designed to allow relators to proceed with a *qui tam* action even after the United States has declined to intervene. If relators' ability to plead sufficiently the element of materiality were stymied by the government's choice not to intervene, this would undermine the purposes of the Act."). Relators litigating declined matters have contributed to the Government's efforts to enforce the False Claims Act by recovering nearly $3 billion for taxpayers ***in declined matters alone*** since 1986. *See* U.S. Department of Justice, Fraud Statistics — Overview, at 1–3, *available at* https://www.justice.gov/opa/press-release/file/1354316/download (last visited March 5, 2021). Since 2017, recoveries ***in declined matters*** have topped $1 billion. *Id.* Plainly the statutory provisions permitting relators to litigate False Claims Act matters after the Department of Justice has declined are a significant and important component of the statutory structure, and should not be undermined by creating a barrier to such litigation.

Finally, the government may elect not to intervene in a particular case for numerous reasons that have nothing do with the materiality of the alleged false statements or false claims. *See United*

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that the intervention decision is relevant to materiality are incorrectly decided. *See United States ex rel. Armstrong v. Andover Subacute & Rehab Ctr. Sers. One, Inc.*, Civ. Action No. 12-3319, 2020 WL 7640535, at *6 (D.N.J. Dec. 22, 2020) (collecting cases). Instead, the correct view is for the factfinder not to consider the Government's decision not to intervene. *See United States ex rel. Sirls v. Kindred Healthcare, Inc.*, Civ. Action No. 16-683, 2021 WL 409981, at *8 (E.D. Pa. Feb. 5, 2021) (noting that it was following the "overwhelming weight of authority" (quoting *United States ex rel. Spay v. CVS Caremark Corp.*, 913 F. Supp. 2d 125, 144 n.3 (E.D. Pa. 2012) (collecting cases))). In addition, the few cases to have deviated from this view (cited in *Armstrong*, above) were decided at the summary judgment, not the motion to dismiss, stage of the action. Given the lack of other evidence of materiality offered by plaintiff-relators in those cases, the courts' statements that the declination decision is relevant (but weighs against materiality), is at best dicta. And certainly should not be the basis for a motion to dismiss.

States ex rel. Chandler v. Cook Cnty., 277 F.3d 969, 974 n.5 (7th Cir. 2002), *aff'd* 538 U.S. 119 (2003). For example, the Department of Justice may decide not to intervene in a case in which it determines that its resources should be expended elsewhere and/or where it believes that relator's counsel is well-positioned to litigate the matter successfully. *See id; United States ex rel. Williams v. Bell Helicopter Textron Inc.*, 417 F.3d 450, 455 (5th Cir. 2005) ("[A] a decision not to intervene may 'not [necessarily be] an admission by the United States that it has suffered no injury in fact, but rather [the result of] a cost-benefit analysis.'" (quoting *United States ex rel. Berge v. Bd. of Trs. of the Univ. of Ala.*, 104 F.3d 1453, 1458 (4th Cir. 1997))); *United States ex rel. Downy v. Corning, Inc.*, 118 F. Supp. 2d 1160, 1170 (D.N.M. 2000). The Department of Justice also may decide not to intervene in an action if it has had insufficient time to investigate relator's allegations and make an intervention decision. The reason (or reasons) for the declination in any given case is privileged information. Guessing that the reason is related to materiality is just that — a guess — and not relevant evidence.

IV. SCIENTIFIC AND MEDICAL EVIDENCE MAY BE RELEVANT TO THE FALSE CLAIMS ACT'S KNOWLEDGE REQUIREMENT

Defendants argue that the medical necessity and reasonableness determination involves some medical judgment and hence cannot be "objectively untrue," which to Defendants implies that this type of claim cannot be made with requisite scienter. (Mem. at 28–29.) The Third Circuit has rejected this argument: "we reject the District Court's bright-line rule that a doctor's clinical judgment cannot be 'false.' " *United States ex rel. Druding v. Care Alternatives*, 952 F.3d 89, 98 (3d Cir. 2020), *cert. denied*, No. 20-371, 2021 WL 666386 (Feb. 22, 2021). Instead, it held that scientific and medical opinion evidence can be presented to a jury to prove the falsity of a claim. *Id.* at 97. The Third Circuit also agreed with the Tenth Circuit that a claim can be legally false because there was insufficient medical or scientific support that a medical procedure was

reasonable and necessary. *Id.* (discussing *United States ex rel. Polukoff v. St. Mark's Hosp.*, 895 F.3d 730, 742–43 (10th Cir. 2018)).[4]

Based on *Care Alternatives*, it is settled in the Third Circuit that falsity can be proven based on medical or scientific opinions of experts that show that a pharmaceutical drug, medical device, or medical procedure was unnecessary or unreasonable in a given situation. Thus, well-pleaded allegations to the same effect should be acceptable to overcome a motion to dismiss.

A jury is capable of deciding whether a defendant believed that its representation was false or whether the representation was factually, scientifically, or medically unsound, even if the representation involved a scientific or medical issue. Similarly, a jury may reasonably conclude that the actions of physicians do not break the causal chain between a company's promotion and the submission of false claims, as a defendant marketing a drug can reasonably foresee that its conduct will cause physicians to prescribe the drug for uncovered uses (or, in this case, unreasonable uses) and pharmacies to submit false claims to the Government. *See United States ex rel. Brown v. Celgene Corp.*, No. 10-3165, 2014 WL 3605896, at *8 (C.D. Cal. July 10, 2014) ("To suggest that Celgene's alleged expansive, multi-faceted efforts to create an off-label market for Thalomid and Revlimid did not cause physicians to prescribe Thalomid or Revlimid for non-reimbursable uses strains credulity. It is implausible that a fraudulent scheme on the scope of that alleged by Brown would be entirely feckless."). Based on traditional principles of causation in tort law, defendants may be held liable under the FCA for causing others to submit false claims. *See*

[4] In addition, the Supreme Court's decision in *Escobar* does not require a plaintiff to plead that a claim for payment made an express representation about the goods or services provided. *Escobar* did not overturn the Third Circuit's pre-existing holding that a defendant can be found liable for violating the False Claims Act under an implied false certification theory of liability even without any express representations to the Government. *See United States ex rel. Wilkins v. United Health Group, Inc.*, 659 F.3d 295, 305 (3d Cir. 2011) (citations omitted) (implied false certification theory premised on notion that act of submitting claim implies compliance with governing rules).

United States ex rel. Hutcheson v. Blackstone Med., Inc., 647 F.3d 377, 391–92 (1st Cir. 2011); *United States ex rel. Sikkenga v. Regence Bluecross Blueshield*, 472 F.3d 702, 714 (10th Cir. 2006); *United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 244–45 (3d Cir. 2004).

Finally, Defendants' reliance on *United States ex rel. Wang v. FMC Corp.,* 975 F.2d 1412 (9th Cir. 1992), is also misplaced. (Mem. at 29.) In that case, relator had failed to produce at the summary judgment stage, any evidence of a lie, rather than an unknowing error. *See* 975 F.2d at 1421 (affirming summary judgment where plaintiff "has not produced evidence that [defendant] acted with the intent requisite for liability under the Act."). The court did ***not*** hold that a defendant is entitled to dismissal at the pleading stage any time it seeks to defend a FCA action based on what knowledge it may or may not have had about the scientific or medical matters at issue.

The Court's resolution of the scienter issue should therefore clarify that a complaint should not be dismissed at the pleading stage for lack of adequate allegations relating to scienter solely because the alleged false claims relate to scientific or medical issues. Whether Defendants knew, prior to the Plavix label revisions in May 2009 that Plavix was ineffective for some patients and nonetheless represented that it was effective for everyone are disputed facts that cannot be resolved on a motion to dismiss.

CONCLUSION

For the foregoing reasons, the Court's decision in this case should reflect that: (i) the FCA's falsity and materiality requirements can be satisfied even when the alleged use of a prescription drug is within the FDA-approved label; (ii) a government agency's continued payment is not dispositive at the pleading stage with respect to the FCA's materiality requirement; (iii) the Department of Justice's nonintervention in a *qui tam* matter is irrelevant to materiality; and (iv)

scienter can be pleaded where a claim involves an allegedly false opinion of medical reasonableness and necessity.

Dated: March 19, 2021
Newark, New Jersey

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Andrew A. Caffrey, III, hereby certify that on March 19, 2021, I caused a copy of the foregoing document to be served by email upon the following counsel of record:

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I further certify that on March 19, 2021, I caused two courtesy copies of the aforementioned documents to be sent to the Honorable Freda L. Wolfson, U.S.D.J. at the Clarkson S. Fisher Federal Building & United States Courthouse, 402 East State Street, Trenton, New Jersey 08609 via Federal Express.

I further certify that on March 19, 2021, I caused two courtesy copies of the aforementioned documents to be sent to the Honorable Tonianne J. Bongiovanni, U.S.M.J. at the Clarkson S. Fisher Federal Building & United States Courthouse, 402 East State Street, Trenton, New Jersey 08609 via Federal Express.

I certify under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Dated: March 19, 2021
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/s/ Andrew A. Caffrey, III
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