No. 20-

In the Supreme Court of the United States

BRISTOL-MYERS SQUIBB CO., SANOFI-AVENTIS U.S. LLC, SANOFI US SERVICES, INC., FORMERLY KNOWN AS SANOFI-AVENTIS U.S. INC., AND SANOFI-SYNTHELABO INC., PETITIONERS

v.

STATE OF NEW MEXICO *EX REL.* HECTOR BALDERAS, ATTORNEY GENERAL

ON PETITION FOR A WRIT OF CERTIORARI TO THE NEW MEXICO COURT OF APPEALS

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

1. Whether the federal government or a state government, as the real party in interest in a *qui tam* action brought in its name and litigated to judgment with its full knowledge, is bound by a final judgment on the merits when that government has declined to intervene.

2. Whether a state court may establish a novel "public policy" exception to the *res judicata* effect of a concededly final federal judgment when that exception runs to the exclusive benefit of a single party: the government.

PARTIES TO THE PROCEEDINGS

Petitioners Bristol-Myers Squibb Company, Sanofi-Aventis U.S. LLC, Sanofi U.S. Services, Inc., formerly known as Sanofi-Aventis U.S. Inc., and Sanofi-Synthelabo LLC, were defendants in the New Mexico district court, appellees in the New Mexico Court of Appeals, and petitioners in the New Mexico Supreme Court. Respondent the State of New Mexico was plaintiff in the district court, appellee in the New Mexico Court of Appeals, and respondent in the New Mexico Supreme Court.

RULE 29.6 STATEMENT

Petitioner Bristol-Myers Squibb Company has no parent company. No publicly held corporation owns 10% or more of its stock.

Petitioner Sanofi-Aventis U.S. LLC is a single-member limited liability company, whose sole member is petitioner Sanofi U.S. Services Inc. Sanofi, a French corporation that is publicly traded on the Paris exchange and NASDAQ, indirectly owns 100% of any class of the equity interests of petitioners Sanofi U.S. Services Inc. and Sanofi-Synthelabo LLC.

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PETITION FOR A WRIT OF CERTIORARI

OPINIONS BELOW

The New Mexico Supreme Court's orders granting petitioners' petition for a writ of certiorari (App. 22a-23a) and quashing the writ as improvidently granted following full briefing and oral argument (App. 24a-25a) are unreported. The New Mexico Court of Appeals' opinion (App. 1a-20a) is reported at 436 P.3d 724, and its order denying petitioners' motion for rehearing (App. 21a) is unreported. The district court's order denying petitioners' motion to dismiss (App. 26a-29a) is also unreported.

JURISDICTION

The New Mexico Supreme Court quashed the writ of certiorari as improvidently granted on June 5, 2020. App. 24a-25a. The jurisdiction of this Court is invoked under 28 U.S.C. 1257(a).

RULE INVOLVED

Federal Rule of Civil Procedure 41(b) states:

Rule 41. Dismissal of Actions

(b) INVOLUNTARY DISMISSAL; EFFECT. If the plaintiff fails to prosecute or to comply with these rules or a court order, a defendant may move to dismiss the action or any claim against it. Unless the dismissal order states otherwise, a dismissal under this subdivision (b) and any dismissal not under this rule—except one for lack of jurisdiction, improper venue, or failure to join a party under Rule 19—operates as an adjudication on the merits.

STATEMENT

The issues presented in this matter reflect an important and growing disagreement among the federal (and now, state) courts: Does a judgment dismissing a *qui tam* suit brought under a federal or state False Claims

Act ("FCA") for failure to state a claim preclude that suit's governmental real parties in interest from pursuing a second lawsuit against the same defendants based on the same underlying facts. Two federal courts of appeals say yes (the Seventh and Ninth Circuits). And two say no (the Fifth and Eleventh Circuits). In the decision below, the New Mexico Court of Appeals sided with the Fifth and Eleventh Circuits in holding that the State of New Mexico was free to sue petitioners even though a relator had already sued them on the State's behalf based on the same facts—and lost. These courts authorize federal and state governments to get a second bite at the apple in every False Claims Act *qui tam* suit that is filed; if the relator's claim is dismissed while litigating in the government's name and on its behalf, the government can simply claim a do-over and file a second suit itself.

Bedrock principles of federal *res judicata* (or "claim preclusion") do not allow such gamesmanship. Each litigant gets "only one full and fair opportunity to litigate" a claim, *United States* v. *Mendoza*, 464 U.S. 154, 159 (1984) (internal quotation marks omitted), and "[a] final judgment on the merits of an action precludes the parties or their privies from relitigating issues that were or could have been raised in that action." *Rivet* v. *Regions Bank of La.*, 522 U.S. 470, 476 (1998) (quoting *Federated Dep't Stores* v. *Moitie*, 452 U.S. 394, 398 (1981)). As this Court emphasized earlier this year, once an earlier suit has reached judgment, that "judgment prevents litigation of all grounds for * * * recovery that were previously available to the parties, regardless of whether they were asserted or determined in the prior proceeding." *Lucky Brand Dungarees, Inc.* v. *Marcel Fashions Grp., Inc.*, 140 S. Ct. 1589, 1594 (2020) (internal quotation marks and citations omitted). And "[s]uits involve the same claim (or 'cause of action') when they aris[e] from the same transaction, or involve a common nucleus of operative

facts." *Id.* at 1595 (internal quotation marks and citations omitted). These principles have important, real-world consequences: They "relieve parties of the cost and vexation of multiple lawsuits, conserve judicial resources, * * * prevent[] inconsistent decisions," and, when enforced by state courts, "promote the comity between state and federal courts that has been recognized as a bulwark of the federal system." *Allen* v. *McCurry*, 449 U.S. 90, 94, 96 (1980).

In the name of public policy, the New Mexico Court of Appeals created a novel exception to federal *res judicata* doctrine, guaranteeing states and the federal governments multiple opportunities in every *qui tam* action. The ruling permits the government to explicitly authorize a *qui tam* suit to proceed on its behalf in federal court and allow the case to unfold without risk. If the relator wins, the State receives the bulk of the judgment. But if the relator's complaint is dismissed, the State would have an absolute right to start over again by filing its own action in state court, treating the relator's earlier lawsuit as a dress rehearsal for its own.

The New Mexico Court of Appeals' "heads we win, tails you lose" rule permits—indeed *encourages*—textbook acts of claim-splitting. At the same time, this rule *discourages* the government from intervening in or consolidating *qui tam* actions because it will *always* have two chances to advance a given claim. This case is a perfect example. Here, the State of New Mexico, through its authorized *qui tam* relator, sued petitioners in the State's name in federal court under New Mexico law, alleging petitioners made misleading statements in marketing Plavix. While that case was pending, the State hedged its bets, authorizing private plaintiffs' attorneys to bring a second suit in its name in state court, advancing related state-law fraud claims based on the same transaction or occurrence. The trial court recognized that

the "claims in both cases appear[] to arise out of common facts," App. 91a, and accordingly urged the State to consolidate its claims in one court because "there is something that seems unfair about having to defend in two jurisdictions," App. 83a. The State *agreed*, saying "you are right" and "that's a very fair point." *Ibid.* But New Mexico chose to proceed with both suits, and the federal court later dismissed New Mexico's suit for failure to state a claim. *United States ex rel. Dickson* v. *Bristol-Myers Squibb Co.* ("*Dickson*"), 332 F. Supp. 3d 927 (D.N.J. 2017) (reproduced at App. 130a-183a). Although the New Mexico Court of Appeals acknowledged "the general rule that a dismissal under Rule 12(b)(6) is an adjudication on the merits for claim preclusion purposes," App. 19a, it invented a novel exception to *res judicata* principles because of a perceived policy interest in permitting "a later potentially successful suit that might result in a large recovery for the government," App. 18a (internal quotation marks, citation, and brackets omitted). It therefore held that the earlier federal dismissal was "without prejudice to the government" bringing a second suit later based on the same claims. App. 19a.

The New Mexico Court of Appeals' decision exacerbates a circuit split that has long destabilized *qui tam* litigation. Consistent with this Court's conclusion that "the United States is bound by the judgment in all FCA actions regardless of its participation in the case," *United States ex rel. Eisenstein* v. *City of New York*, 556 U.S. 928, 936 (2009), the Seventh and Ninth Circuits have rightly concluded that dismissal of a relator's *qui tam* claims binds the state and federal governments that are the real parties in interest. See *United States ex rel. Lusby* v. *Rolls-Royce Corp.*, 570 F.3d 849, 852-853 (7th Cir. 2009); *Stoner* v. *Santa Clara Cnty. Off. of Educ.*, 502 F.3d 1116, 1126 (9th Cir. 2007). If the relator wins, the government wins; but if the relator loses, the government

may not relitigate the same claims. The Fifth and Eleventh Circuits, by contrast, have created exceptions to this rule for federal judgments still open on appeal, holding that dismissal of a relator's lawsuit is ordinarily "without prejudice to the government" in cases in which the government has not intervened. See *Urquilla-Diaz* v. *Kaplan Univ.*, 780 F.3d 1039, 1057 (11th Cir. 2015); *United States ex rel. Williams* v. *Bell Helicopter Textron, Inc.*, 417 F.3d 450, 455-456 (5th Cir. 2005). Under the rule in those circuits, if the relator wins, the government wins. But if the relator's complaint is dismissed, the government is not bound by that defeat and remains free to pursue its claims anew against the same defendants.

Not only does the decision below exacerbate this split, it goes even further, extending the Fifth and Eleventh Circuit's exception to apply to collateral attacks on a final judgment. While previous courts have allowed government entities to request modification of a still-open judgment to explicitly state it is without prejudice to the government, the New Mexico Court of Appeals extended that rationale *to collateral review* of what it conceded was a final federal judgment, thereby creating a novel "public policy" exception to ordinary *res judicata* principles. Particularly in view of the rising tide of *qui tam* litigation under both the federal FCA and ubiquitous state analogues, this Court's review is warranted to address this critically important issue.

A. New Mexico Authorized A *Qui Tam* Suit To Proceed In Its Name In Federal Court—And Therefore Stood To Share In Any Recovery

In March 2011, *qui tam* relator Elisa Dickson sued petitioners in federal court, alleging that they misrepresented the effectiveness of the prescription antiplatelet drug Plavix to prescribing doctors, Medicare, and state Medicaid programs and caused the submission of fraudulent payment claims to those government

programs. Dickson brought the action on behalf of, and in the name of, the federal government, New Mexico, and 23 other states, alleging violations of the federal FCA, the New Mexico Medicaid FCA, NMSA 1978, §§ 27-14-1 *et seq.* ("New Mexico FCA"), and other states' similar laws. App. 133a, 135a-136a & n.2. Like many other *qui tam* statutes, the New Mexico FCA requires the state to be notified before the case is unsealed and given an opportunity to intervene or dismiss the case. NMSA §§ 27-14-7, 27-14-8.[1] The New Mexico FCA further provides that the State, upon receiving a complaint, "shall conduct an investigation of the factual allegations and legal contentions" and must "make a written determination of whether there is substantial evidence that a violation has occurred" before the *qui tam* claim can proceed. NMSA § 27-14-7(C). The State's options are to intervene, to allow the relator to proceed on its behalf without intervening, to dismiss the action, or to settle. See NMSA §§ 27-14-7, 27-14-8.

Several other states—Hawaii, Louisiana, and Mississippi—later chose to withdraw the *Dickson* relator's state-law claims in favor of pursuing their claims separately in their respective state courts. But following its investigation in September 2012, New Mexico declined either to intervene or to dismiss the claims. App. 83a-85, 92a, 134a. The State thus remained a real party in interest in the lawsuit, retaining the right to intervene at a later date or dismiss the claim at any time. NMSA 1978, § 27-14-8(B), (D), (E). If the relator succeeded, the State stood to gain at least 70 percent of any recovery, without

[1] Thirty-one states and nine counties have enacted analogous FCA statutes. See 6 Joel Androphy, *White Collar Crime* § 42:32 (2d ed.) (updated July 2020). There is substantial similarity among state and federal FCA statutes. See pp. 25-26 & n.8, *infra*.

expending any resources to litigate the case. *Id.* § 27-14-9(B).

B. New Mexico Initiated A Duplicative Parallel State-Court Lawsuit

In September 2016, while *Dickson* was being actively litigated, New Mexico brought this parallel suit in state court through private plaintiffs' lawyers, alleging that petitioners misleadingly promoted Plavix and caused the submission of fraudulent payment claims to New Mexico's Medicaid program. App. 6a, 30a-73a. Instead of suing under the New Mexico FCA, however, the State alleged various alternative statutory violations, including claims under the state Unfair Practices Act, Medicaid Fraud Act, Fraud Against Taxpayers Act, as well as common-law theories of fraud, negligence, and unjust enrichment. App. 30a-73a.

Petitioners moved to dismiss or stay the case in favor of *Dickson*, arguing that the State had improperly split its claims. During oral argument, the state district court raised concerns that this action was duplicative of New Mexico's federal suit. In response, the State conceded that the matters arose from a common nucleus of operative facts and agreed to consider consolidating the two actions:

> THE COURT: Okay. And so your answer to why the State of New Mexico and the attorney general's office did not tell [the *Dickson*] court to get lost, we want to pursue our own claim, is they didn't need to? * * * Seriously, I'm wondering, because *there is something that seems unfair about having to defend in two jurisdictions.*
>
> MR. ALBERSTONE [private counsel for the State]: Let me explain something, Your Honor. *You are right*, and I'm going to consult with the client about that; *I think that's a very fair point.*

App. 83a (emphases added). The State's counsel noted that "there are differences [between *Dickson* and this case], but I'm not going to argue * * * the common nucleus of facts aren't there." App. 105a.

The New Mexico district court concluded that the claims asserted in the State's complaint and the claims asserted on its behalf in *Dickson* shared "common facts," App. 91a, because both cases arose from petitioners' alleged false, deceptive, and unfair labeling and promotion of Plavix, App. 95a. The district court thus granted petitioners' motion to stay "to give [the State] the opportunity to dismiss the [*Dickson*] case" or "consolidate everything that can be brought in the New Mexico Case." App. 89a-90a; see App. 91a-92a.

The State, however, chose not to consolidate the suits. Instead, it awaited the outcome in *Dickson*.

C. After The Federal Court Dismissed New Mexico's Claims On The Merits, The New Mexico State Courts Gave The State A Second Chance To Pursue Those Claims In State Court

After six years of litigation and five separate complaints, the *Dickson* court in June 2017 granted petitioners' third motion to dismiss the case, holding that, under Rule 12(b)(6), the relator's "specific allegations," App. 158a, showed she "*could not*" establish that supposed misrepresentations about Plavix's effectiveness were material under *Universal Health Services* v. *United States ex rel. Escobar*, 136 S. Ct. 1989 (2016), App. 161a (emphasis added). The court explained that, because the relator's complaint "clearly allege[d] that once the claims for Plavix were submitted to Medicaid [and] were paid automatically by virtue of Plavix's inclusion" on the State's list of preferred medications, the supposed misrepresentations were not material because they could not possibly have affected payment decisions. App. 161a. The district court stated without qualification that

"Relator's Fourth Amended Complaint is DISMISSED." App. 185a. Neither the relator, the State of New Mexico, nor any other government entity sought to amend or clarify the judgment, challenge the dismissal's scope, or appeal the decision.

After *Dickson*'s dismissal in federal court, petitioners moved to dismiss the state-court case on *res judicata* grounds. But despite the district court's earlier observation that the suits shared common operative facts, and despite the State's concessions on that point, the New Mexico court held that "*res judicata* does not apply here because the causes of action are not the same in the two suits." App. 28a. The court focused only on those legal theories that actually *were* raised in the federal court action, not those that "*could have been raised* in that action." *Moitie*, 452 U.S. at 398 (emphasis added). The district court acknowledged that "the relator could have asserted the State's [Fraud on the Taxpayer Act] claim in *Dickson*"; moreover, it noted that "[i]f the State had intervened in *Dickson*, the State could have asserted [all of its] claims, but the State elected not to intervene."[2] App. 28a.

The New Mexico Court of Appeals affirmed on a different basis. App. 1a-20a. The court acknowledged that, because *Dickson* proceeded in federal court, "federal

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[2] In *dicta*, the New Mexico district court stated it would also "be inappropriate to bar the State's claims" "where the relator's claims were dismissed based on a failure to comply with the heightened pleading requirements of Rule 9(b)." App. 28a. However, the "pleading requirements" at issue in *Dickson* derived not from Rule 9(b), but *Escobar*. The *Dickson* court had previously rejected petitioners' Rule 9(b) claims as "misplaced," and in dismissing, it noted petitioners' Rule 9(b) arguments about the Fourth Amended Complaint were "substantially similar" to those it had previously rejected. App. 150a. The court instead held that the allegations "fail to plead materiality [under *Escobar*], and therefore do not state a cause of action * * * ." App. 162a.

law governs the preclusive effect that the prior federal judgment should have on these state court proceedings." App. 8a (internal quotation marks omitted). "[B]ecause the [*Dickson*] order did not provide for a fifth amendment [to the complaint] and disposed of all of Relator's claims," the court of appeals "construe[d] it as an adjudication on the merits as to Relator, consistent with the general rule that a dismissal under Rule 12(b)(6) is an adjudication on the merits for claim preclusion purposes." App. 19a. The court observed that some federal courts of appeals, on direct appeal before the judgments had become final (and at the urging of the federal government as the real party in interest), had modified dismissals in non-intervened *qui tam* cases so the dismissals were entered without prejudice to the government. App. 11a (citing *United States ex rel. Williams* v. *Bell Helicopter Textron, Inc.*, 417 F.3d 450, 455-456 (5th Cir. 2005)). The court observed that "claim preclusion in the *qui tam* context could operate adverse to the public interest," by potentially "bar[ring] a later potentially successful suit that might result in a large recovery for the government." App. 18a (internal quotation marks, citation, and brackets omitted). Extending the rationale of *Williams* from judgments still open on direct appeal to the context of final judgments, the court held that the *Dickson* dismissal was "on the merits" as to the relator but "without prejudice" as to the State. App. 19a-20a The Court of Appeals denied petitioners' timely rehearing petition. App. 21a.

The New Mexico Supreme Court granted certiorari, and the parties fully briefed the case. App. 24a-25a. Oral argument was then heard by an even number of justices (four) following the Chief Justice's retirement announcement and decision not to participate in this case.[3] *Ibid.*

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[3] Phaedra Haywood, *Chief Justice Nakamura's Still Retiring, But Not Yet*, Albuquerque J. (June 27, 2020), https://perma.cc/2B2P-ASU9 (retirement originally scheduled for June 1, 2020).

Three weeks after hearing oral argument, the court on June 5, 2020, quashed the writ as improvidently granted without explanation. *Ibid.* That court has stayed its mandate pending the filing of this petition. See Order Granting Motion to Stay Mandate, *New Mexico ex rel. Balderas v. Bristol-Myers Squibb Co.*, No. S-1-SC-37430 (N.M. June 24, 2020).

REASONS FOR GRANTING THE PETITION

The decision of the New Mexico Court of Appeals highlights the growing divide among federal (and now state) courts regarding the binding effect on the government in an all too common scenario—when a federal court has dismissed a relator's FCA lawsuit for failure to state a claim and the government has chosen not to intervene, but remains a real party in interest. *Res judicata* plays an integral role in our judicial system by "protect[ing] against the expense and vexation attending multiple lawsuits, conserv[ing] judicial resources, and * * * minimizing the possibility of inconsistent decisions." *Taylor* v. *Sturgell*, 553 U.S. 880, 892 (2008) (internal quotation marks and citations omitted). The New Mexico Court of Appeals did not contest that the ordinary elements for *res judicata* were satisfied in this case. Instead, that court simply "constru[ed] the [*Dickson*] order as without prejudice to the government," App. 19a, because of its policy concerns that "claim preclusion in the *qui tam* context could operate adverse to the public interest." App. 15a; accord App. 11a ("the government's role in vindicating public interests militates against preclusion of its claims") (citing Nathan D. Sturycz, Comment, *The King and I?: An Examination of the Interest* Qui Tam *Relators Represent and the Implications for Future False Claims Act Litigation*, 28 St. Louis U. Pub. L. Rev. 459, 462-463 (2009)).

Thus, instead of applying traditional *res judicata* principles, the New Mexico Court of Appeals has

endorsed an exception for state and federal governments: In *qui tam* actions, the government can sit back and reap the benefits if the relator prevails in her lawsuit, but it remains free to bring a second lawsuit based on the same operative facts even where the relator's complaint is dismissed with prejudice. This exception conflicts with principles of *qui tam* law and recent pronouncements of this Court; it also has divided the circuits, creating uncertainty about the binding effect of a type of litigation that accounts for an ever-larger share of federal and state dockets; and in the process, it has encouraged duplicative litigation. This Court's review is urgently needed.

I. THE NEW MEXICO DECISION EXACERBATES AN EXISTING SPLIT OF AUTHORITY

This Court should grant review to resolve a split of authority on a core question of *qui tam* litigation: whether a "with prejudice" dismissal order against a relator in a *qui tam* action is in fact "with prejudice" to the government when the government has not intervened. See *United States* v. *Whyte*, 918 F.3d 339, 350 n.10 (4th Cir. 2019) (acknowledging conflicting circuit precedent but declining to "take issue with those courts holding that the Government may be bound (for some purposes) by an FCA action in which it did not intervene"); cf. *United States ex rel. Charte* v. *Am. Tutor, Inc.*, 934 F.3d 346, 356 (3d Cir. 2019) (Hardiman, J., dissenting) (recognizing the "procedural brainteasers *qui tam* preclusion might offer"). The decision below exacerbates this split. As noted by the very authority that the Court of Appeals cited: "In the face of the ever-growing wave of FCA and *qui tam* actions * * * it is likely that such confusion over the relator-government relationship will persist" absent guidance from this Court. Sturycz, 28 St. Louis U. Pub. L. Rev. at 463. In light of "the consistently high number of *qui tam* actions" courts have seen in recent years, *ibid.*, this Court's immediate review is warranted. See Dep't of

Justice, *Justice Department Recovers over $3 Billion from False Claims Act Cases in Fiscal Year 2019* (Jan. 9, 2020), https://perma.cc/94BA-VXUU ("[t]his is the tenth consecutive year" that FCA recoveries have exceeded $2 billion).

A. The Fifth and Eleventh Circuits Have Held That "With Prejudice" *Qui Tam* Dismissals Should Exempt The Government For Policy Reasons

The Fifth and Eleventh Circuits have held that the government should not be bound by "with prejudice" judgments dismissing relators' *qui tam* actions when the government does not intervene. See *Urquilla-Diaz* v. *Kaplan Univ.*, 780 F.3d 1039, 1057 (11th Cir. 2015); *United States ex rel. Williams* v. *Bell Helicopter Textron, Inc.*, 417 F.3d 450, 455-456 (5th Cir. 2005).

The leading case adopting this theory is the Fifth Circuit's decision in *Williams*. In *Williams*, the district court dismissed a *qui tam* action "with prejudice" to both the relator and the government for failing to satisfy Rule 9(b)'s requirement of pleading fraud with particularity. See 417 F.3d at 454. Although the government had chosen not to intervene in the district court, it intervened on appeal, arguing that the dismissal order should be modified to specify that it was made "without prejudice" to the government. *Id.* at 452. A divided panel of the Fifth Circuit held that the district court erred in dismissing the complaint with prejudice to the government, citing two factors. First, the court of appeals rejected the district court's conclusion that the government's failure to intervene necessarily reflected a conclusion that the *qui tam* action lacked "the slightest merit"; instead, the Fifth Circuit recognized the government's failure to intervene might represent a "cost-benefit analysis." *Id.* at 455. Second, the court majority held as a matter of policy that a contrary ruling would give "private parties * * * the added incentive to file FCA suits lacking in the required

particularity, knowing full well that the government would be obligated to intervene and ultimately 'fill in the blanks' of the deficient complaint" to avoid a "with prejudice" dismissal. *Ibid.* Accordingly, the Fifth Circuit held that, while a Rule 9(b) dismissal could be "with prejudice" as to the relator, the district court abused its discretion in holding it was also "with prejudice" to the government. Judge Edith Jones noted her dissent from this part of the decision. See *id.* at 452 n.1.

Although *Williams* involved the relator's failure to plead fraud with particularity, courts have extended its reasoning to cases involving dismissal for failure to state a claim. For example, in *Urquilla-Diaz*, the Eleventh Circuit affirmed the dismissal of a relator's non-intervened FCA action for failure to state a claim under 12(b)(6). 780 F.3d at 1057. The court of appeals *sua sponte* "modif[ied] the judgment of dismissal to be without prejudice to the government," in an evident effort to foreclose arguments "that *res judicata* bars the government from bringing a properly pleaded False Claims Act action" against the defendant in the future. *Ibid.*

Based on *Williams* and its progeny, the federal government has adopted the practice of filing "notices of interest" in *qui tam* cases in which it has not intervened, asking courts to specify that the dismissal orders be without prejudice to the government. District courts routinely oblige. See, *e.g.*, *United States* v. *KForce Gov't Sols., Inc.*, No. 8:13-CV-1517-T-36TBM, 2014 WL 5823460, at *9 (M.D. Fla. Nov. 10, 2014) ("Count I will be dismissed with prejudice as to [relator] and without prejudice as to the United States."); *United States ex rel. Jean-Louis* v. *City of Riverside*, No. EDCV 17-00379 AG(ASx), 2019 WL 1877601, at *3 (C.D. Cal. Jan. 9, 2019) (similar); *United States ex rel. Rostholder* v. *Omnicare, Inc.*, No. 07-cv-1283, 2012 WL 3399789, at *15 (D. Md.

Aug. 14, 2012) ("[I]t would be inappropriate to dismiss with prejudice as to the United States[.]"), aff'd, 745 F.3d 694 (4th Cir. 2014).[4]

B. The New Mexico Court of Appeals Broadens The Government Exemption

The New Mexico Court of Appeals' decision expanded the holding of *Williams* in two important respects. First, while *Williams*' actual holding only dictates exempting the government from dismissal with prejudice when the relator's complaint is dismissed for a technical pleading deficiency under Rule 9(b), see 417 F.3d at 454, the Court of Appeals read it to create a sweeping rule freeing the government from the binding effect of any dismissal for failure to state a claim in a non-intervened case. See App. 18a ("The *Williams* holding was not limited to the Rule 9(b) pleading standard."). Because *any* Rule 12(b)(6) dismissal is "based only on the relator's complaint, not the factual bases underlying the allegations," App. 11a, the New Mexico Court of Appeals reasoned that "such a [Rule 12(b)(6)] dismissal does not preclude the government's claims when the government has not intervened," *ibid.* Thus, while the court acknowledged that *Dickson* was "an adjudication on the merits as to Relator, consistent with the general rule that a dismissal under Rule 12(b)(6) is an adjudication on the merits for claim preclusion purposes," App. 19a, it held that *Dickson*'s judgment "on the merits" did not bind the State because "claim preclusion in the *qui tam* context could operate adverse to the public interest," App. 15a. In other words, only summary judgment or a trial verdict for a *qui tam* defendant would bind the government—if it could ever be bound at all.

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[4] See also, *e.g.*, Sturycz, 28 St. Louis U. Pub. L. Rev. at 462-463 (arguing that claim preclusion should not "provide a defense to repetitive claims" in the *qui tam* context).

The decision below expanded *Williams* in a second respect. *Williams* and the other cases in that line involved federal courts modifying judgments that were still open on appeal—*i.e.*, a non-final judgment for *res judicata* purposes—to explicitly specify that they were without prejudice to the real party in interest: the government. The New Mexico Court of Appeals took that one step further by purporting to construe a *final* judgment of a court of a *different* sovereign that said nothing about exempting the government, and interpreting it to include an exemption that its wording did not support. The actual *Dickson* judgment provided without qualification that the matter was "DISMISSED." App. 184a-185a. The New Mexico Court of Appeals recognized that as a general matter, such an unadorned dismissal constituted "an adjudication on the merits for claim preclusion purposes" under federal law. App. 19a. But from that silent order, the Court of Appeals inferred for policy reasons that the order would not have its ordinary effect against the State of New Mexico. Because the New Mexico Supreme Court declined to rule in this case, the Court of Appeals' decision provides the statewide rule governing all New Mexico courts.[5]

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[5] The New Mexico Supreme Court granted certiorari, received briefing, and, after Chief Justice Nakamura's retirement announcement, heard oral argument with an even number of justices (four) participating. The court quashed the writ without explanation three weeks later. App. 24a-25a. The New Mexico Supreme Court frequently quashes writs of certiorari when it determines after argument that the case does not meet its particular statutory bases for review, which are limited to cases involving (1) a conflict with a decision of the state supreme court or court of appeals, (2) "a significant question of law under *the constitution* of New Mexico or the United States," or (3) an "issue of substantial public interest." See, *e.g.*, *State* v. *Conn*, 847 P.2d 744, 745 (N.M. 1993) (quoting NMSA 1978 §34-5-14(B) (emphasis added)). See generally *Ramah Navajo Sch. Bd., Inc.* v. *Bureau of Revenue of*

C. The Seventh and Ninth Circuits Have Held That A Dismissal Against A *Qui Tam* Relator Binds The Government

By contrast, the Seventh and Ninth Circuits have squarely held that the dismissal of a non-intervened *qui tam* action on the pleadings for failure to state a claim under Rule 12(b)(6) is binding on the government. A state or the federal government "is a 'real party in interest' in a case brought under the FCA" or a state analogue because the action is litigated in its name and to its financial benefit, *Eisenstein*, 556 U.S. at 930, and the government exercises substantial control by its ability to intervene, dismiss, and settle such actions. The Seventh and Ninth Circuits have therefore held that the government and its *qui tam* relator are in privity and that, when a *qui tam* action is litigated to a final judgment, that judgment is binding on both the relator and the government entity in whose name it is brought. See *United States ex rel. Chovanec* v. *Apria Healthcare Grp. Inc.*, 606 F.3d 361, 362 (7th Cir. 2010); *United States ex rel. Lusby* v. *Rolls-Royce Corp.*, 570 F.3d 849, 853 (7th Cir. 2009); *Stoner* v. *Santa Clara Cnty. Office of Educ.*, 502 F.3d 1116, 1126 (9th Cir. 2007); *In re Schimmels*, 127 F.3d 875, 882 (9th Cir. 1997).

As Judge Easterbrook explained, these cases rest on the straightforward principle that "[t]he plaintiff in a *qui tam* action, after all, is the United States rather than the relator," and that accordingly, "whether the United States wins or loses in the initial action, that is the end of the dispute." *Chovanec*, 606 F.3d at 362. "That the [government] is bound is why it is a real party in interest." *Lusby*, 570 F.3d at 853. The Seventh Circuit thus explicitly rejected the notion that a district court could order that "dismissal, though with prejudice to [the

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N.M., 458 U.S. 832, 836 (1982) (granting review of New Mexico Court of Appeals decision after the State's Supreme Court quashed the writ of certiorari).

relator], is without prejudice to the United States," so that "the United States may pursue a suit under the False Claims Act even if a *qui tam* suit has been filed and lost, and even if that loss blocks actions by other relators." *Lusby*, 570 F.3d at 853. It explained: "The Supreme Court thought otherwise in *Eisenstein*." *Ibid.* It is not an option for courts to bend basic rules of claim preclusion to benefit the government as a litigant: Instead, "[t]he [government] must protect its interest by intervening in a *qui tam* action rather than by asserting a right to file a False Claims Act suit after the defendant has prevailed." *Ibid.*

The Ninth Circuit reached the same conclusion in *In re Schimmels*, 127 F.3d at 884. There, the government "admit[ted] that a relator in a *qui tam* action is in privity with the United States 'for some purposes,'" but argued that the relator could not have adequately represented the government's interests in the underlying bankruptcy proceeding that yielded an adverse judgment against the relator. See *id.* at 882. The court rejected the government's partial privity theory, noting that "there is an unity of interest between the relators and the government who will share *any and all* recovery in the *qui tam* action against the [defendants]." *Id.* at 883. Given that unity of interest and the government's authority to intervene in a *qui tam* case, the court held that "the doctrine of *res judicata* applies to parties and their privies, and as the government has been conclusively shown to be in privity with the relators, the involuntary dismissal of the relators' claim [under Federal Rule of Civil Procedure 41(b)] has a preclusive effect not only on the relators, but also on the government." *Id.* at 884. The Second and Fourth Circuits have likewise noted that judgments against relators bind the government in holding that pro se litigants may not serve as relators. See *Wojcicki* v. *SCANA/SCE&G*, 947 F.3d 240, 244 (4th

Cir. 2020) ("Even if the United States does not intervene in a *qui tam* action brought pursuant to the FCA, 'the United States is bound by the relator's actions for purposes of *res judicata*.'") (quoting *Stoner*, 502 F.3d at 1126); see also *United States ex rel. Mergent Servs.* v. *Flaherty*, 540 F.3d 89, 93-94 (2d Cir. 2008).

A number of district courts similarly have dismissed *qui tam* actions with prejudice to the government when it declined to intervene. So long as the government had an opportunity to intervene in the case, these courts have concluded that "[t]o dismiss these claims without prejudice at [the end of a multi-year litigation] would be manifestly unfair to defendants." *United States ex rel. Woods* v. *N. Ark. Reg'l Med. Ctr.*, No. 03-3086, 2006 WL 2583662, at *4 (W.D. Ark. Sept. 7, 2006); see also *United States ex rel. Jones & Wert Constr. Specialties, Inc.* v. *Straub Const., Inc.*, No. 10CV1415 JLS RBB, 2013 WL 4883152, at *3 (S.D. Cal. Sept. 12, 2013) ("A dismissal with prejudice as to [relator] on the basis of *res judicata* would preclude subsequent suits by the Government or other potential relators.").[6]

The circuits are thus intractably divided on the fundamental issue of the preclusive effect of the dismissal of a *qui tam* claim. Only this Court's review can resolve this recurring issue.

II. THE DECISION BELOW IS WRONG

This Court should also grant review to correct the decision below, which, at bottom, represents a state

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[6] See also, *e.g.*, David Freeman Engstrom, *Public Regulation of Private Enforcement: Empirical Analysis of DOJ Oversight of* Qui Tam *Litigation Under the False Claims Act*, 107 Nw. U. L. Rev. 1689, 1710 (2013) ("[B]ecause a relator stands in the shoes of the United States and sues on its behalf, any judgment will have preclusive effect on the government's later assertion of transactionally related claims * * * .").

court's misapplication of federal law to the exclusive benefit of one party—the State. See *Taylor* v. *Sturgell*, 553 U.S. 880, 891 (2008) ("The preclusive effect of a federal-court judgment is determined by federal common law.").

A. Under Federal Law, The *Dickson* Dismissal Was Presumptively An Adjudication On The Merits

The Court of Appeals made a fundamental mistake by holding that the *Dickson* dismissal was without prejudice to the State. The plain text of the Federal Rules makes clear that the dismissal was with prejudice. Federal Rule of Civil Procedure 41(b) provides:

> *Unless the dismissal order states otherwise*, a dismissal under this subdivision (b) and any dismissal not under this rule—except one for lack of jurisdiction, improper venue, or failure to join a party under Rule 19—*operates as an adjudication on the merits*.

Fed. R. Civ. P. 41(b) (emphases added). Earlier this year, and just days after the New Mexico Supreme Court quashed the writ in this case, this Court reaffirmed the plain import of that provision: "When a court dismisses a case for failure to state a claim, but neglects to specify whether the order is with or without prejudice," then "courts [must] treat the dismissal 'as an adjudication on the merits'—*meaning a dismissal with prejudice*." *Lomax* v. *Ortiz-Marquez*, 140 S. Ct. 1721, 1725 (2020); accord *Moitie*, 452 U.S. at 399 n.3 ("[t]he dismissal for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6) is a 'judgment on the merits'" for *res judicata* purposes).

Here, the *Dickson* dismissal order unqualifiedly stated that "Relator's Fourth Amended Complaint is DISMISSED." App. 185a. It did not state that the dismissal was without prejudice to the State of New

Mexico, and it did not give leave to amend. As *Lomax* recently reaffirmed, federal law treats such a dismissal as being "with prejudice" and "a judgment on the merits, with the same preclusive effects as any other valid final judgment." 18 Moore's Federal Practice § 131.30 (2019). The Ninth Circuit has explained in this precise context, "Rule 41(b) and the doctrine of *res judicata* do not * * * operate independently of each other; rather, the latter extends the scope of the former to include not only [the relator], but also those in privity therewith." *Schimmels*, 127 F.3d at 884-885.

B. There Is No Basis For Creating A Public Policy Exception For *Qui Tam* Cases

The New Mexico Court of Appeals expanded *Williams*'s "public policy" exception and applied it in the *res judicata* context. Its decision is squarely foreclosed by this Court's precedent.

In *Moitie*, this Court "consider[ed] the validity of the Court of Appeals' novel exception to the doctrine of r*es judicata*" that was created to allow appellants to benefit from an intervening decision in a related case. 452 U.S. at 398. In rejecting such an exception, this Court reinforced the importance of *res judicata* as a foundational rule that is not subject to *ad hoc* equitable exceptions:

> [W]e do not see the grave injustice which would be done by the application of accepted principles of *res judicata*. "Simple justice" is achieved when a complex body of law developed over a period of years is evenhandedly applied. The doctrine of *res judicata* serves vital public interests beyond any individual judge's *ad hoc* determination of the equities in a particular case. There is simply "no principle in law or equity which sanctions the rejection by a federal court of the salutary principle of *res judicata*."

Id. at 401 (quoting *Heister* v. *Woodruff*, 327 U.S. 726, 733 (1946)).

Nor is there any basis for carving out an exception to *res judicata* for the real party in interest in a *qui tam* lawsuit—the state or federal government. The conclusion that the government is bound by a decision obtained by a *qui tam* relator who litigated on its behalf is firmly grounded in the common law. As Blackstone explained: "But if any one hath begun a *qui tam*, or *popular*, action, no other person can pursue it; and the verdict passed upon the defendant in the first suit is a bar to all others, and *conclusive even to the king himself*." 3 William Blackstone, *Commentaries on the Laws of England* *160 (second emphasis added); accord, *e.g.*, *United States ex rel. Cimznhca, LLC* v. *UCB, Inc.*, No. 19-2273, 2020 WL 4743033, at *8 (7th Cir. Aug. 17, 2020) (quoting Blackstone); *Miami Copper Co.* v. *State*, 149 P. 758, 761 (Ariz. 1915) (same). This Court reaffirmed in *Eisenstein* that that the government "is bound by the judgment in all FCA actions regardless of its participation in the case." 556 U.S. at 936; see also *Lusby*, 570 F.3d at 852.

The *Williams* rationale is that governments should be exempted from *res judicata* effects of non-intervened *qui tam* suits to preserve their ability to pursue claims that might be compromised by relators' counsel. But as this Court has explained, the government has the full ability to protect its own interests: "If the United States believes that its rights are jeopardized by an ongoing *qui tam* action, the FCA provides for intervention." *Eisenstein*, 556 U.S. at 936. There is thus no basis for an equitable rule exempting the government from ordinary principles of *res judicata*: "The [government] must protect its interest by intervening in a *qui tam* action rather than by asserting a right to file a False Claims Act suit after the defendant has prevailed." *Lusby*, 570 F.3d at 853. The government need not litigate the case to

protect its interest; it can intervene simply to dismiss the action, and thereby eliminate the risk of an adverse precedent. See, *e.g.*, *Cimznhca*, 2020 WL 4743033, at *1.

The State of New Mexico likewise had the full statutory authority to protect its interests in *Dickson* by intervening, dismissing, or settling the State's claims in that case. Indeed, this litigation was stayed for the very purpose of allowing the State to exercise those authorities in *Dickson* after the State acknowledged "that's a very fair point," and that it was "unfair" that petitioners "ha[d] to defend in two jurisdictions" against the same claims. App. 83a. As one district court explained, "[t]o dismiss these claims without prejudice at this juncture," thereby exempting the government from the ordinary principles of *res judicata* after it stood by during years of *qui tam* litigation conducted with its full knowledge, "would be manifestly unfair to defendants." *Woods*, 2006 WL 2583662, at *4.

C. The Decision Below Violates Core Federalism Principles

The Court of Appeals' decision violated a core principle of federal supremacy that "State courts have no power to revise the action of the Federal courts." *Claflin* v. *Houseman*, 93 U.S. 130, 137 (1876); *Mondou* v. *New York, N.H. & H.R. Co.*, 223 U.S. 1, 58 (1912) (same); see U.S. Const. Art. VI, Cl. 2. As noted above, the *Dickson* dismissal, which said nothing about exempting the State from its *res judicata* effects, was presumptively with prejudice to both the relator and the State, as the real party in interest. In the guise of "construe[ing] the [*Dickson* dismissal] order as without prejudice to the government," App. 19a, the Court of Appeals—sitting in

collateral review of the federal judgment—added terms nowhere present in the order and changed its meaning.[7]

That was impermissible, in plain violation of "the comity between state and federal courts that has been recognized as a bulwark of the federal system." *Allen*, 449 U.S. at 96. This Court "ha[s] long held that States cannot give [federal court] judgments merely whatever effect they would give their own judgments, but *must accord them the effect that this Court prescribes*." *Semtek Int'l Inc.* v. *Lockheed Martin Corp.*, 531 U.S. 497, 507 (2001) (emphasis added). "The requirement that federal court judgments command at least the central core of *res judicata* effects in state courts is indispensable to federalism." *Williams Nat. Gas Co.* v. *City of Okla. City*, 890 F.2d 255, 265 n.11 (10th Cir. 1989) (internal quotation marks omitted). If the State had wanted to exempt itself from the binding effect of *Dickson*, it should have done as the federal government has done countless times, see pp. 14-15, *supra*, and requested that the federal district court modify its order to exempt the State, or sought to appeal. Having neglected to do so, the *Dickson* dismissal "[was] not open to collateral attack," *Moitie*, 452 U.S. at 398, and the state court was not free to give the now-final federal judgment a different effect than its plain terms dictated.

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[7] Given the federal interests at issue, this case is comfortably within the jurisdictional ambit of *Cox Broadcasting Corp.* v. *Cohn*, 420 U.S. 469, 482-483 (1975), because (1) the federal issue (the *res judicata* effect of a federal case) has been finally decided in state court; (2) petitioners may prevail on non-federal grounds on remand, precluding future review of this issue; (3) reversal of the state court on the *res judicata* issue would resolve the case; and (4) the critical interests in finality of federal judgments would be threatened if review is denied. See *Montana* v. *United States*, 440 U.S. 147, 153 (1979) (identifying systemic federal interests in *res judicata*); *Fort Wayne Books, Inc.* v. *Indiana*, 489 U.S. 46, 55-56 (1989) (granting certiorari to address federal issues arising from state enforcement suits under Indiana RICO statute).

III. THE ISSUE IS IMPORTANT AND RECURRING

The preclusive effect of dismissed *qui tam* cases is unquestionably an important issue. The number of federal *qui tam* actions has mushroomed over the past three decades. See Dep't. of Justice, *Fraud Statistics Overview: Oct. 1, 1986 - Sept. 30, 2019*, at 1 (2019), https://perma.cc/8DYT-3Z5U. From 2010 to 2019, federal district courts fielded an average of 666 claims annually, or nearly 13 new lawsuits each week. State *qui tam* actions have likewise proliferated. Moreover, virtually all non-intervened cases fail, and courts dismiss many of them for failure to state a claim, just as the *Dickson* court did. See Michael Rich, *Prosecutorial Indiscretion: Encouraging the Department of Justice to Rein in Out-of-Control* Qui Tam *Litigation Under the Civil False Claims Act*, 76 U. Cin. L. Rev. 1233, 1264 (2008) ("Ninety-four percent of non-intervened cases result in no recovery."); David O'Neill, *Resolving the Confusion: Granting the Government Unfettered Discretion to Dismiss* Qui Tam *Actions*, 49 Pub. Cont. L.J. 403, 411-410, 418 (2020) (collecting empirical studies and noting that "relators rarely recover money after the government chooses not to intervene in their action"). Moreover, thirty-one states and nine counties have enacted analogous FCA statutes, and Congress has provided a significant financial incentive for more states to follow suit.[8] Many suits combine federal and state FCA

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[8] See 6 Joel Androphy, *White Collar Crime* § 42:32 (2d ed.) (updated July 2020) (cataloguing state and local FCA analogues); Deficit Reduction Act of 2005, Pub. L. No. 109-171, § 6031, 120 Stat. 72-73 (2006); Publication of OIG Guidelines for Evaluating State False Claims Acts, 71 Fed. Reg. 48552 (Aug. 21, 2006). The prerequisites for receiving federal funds under this standard include, *inter alia*, a state provision requiring the action to be filed under seal for 60 days to allow the state attorney general to review it. At least 21 states have passed legislation complying with

claims. This case illustrates that phenomenon: The Fourth Amended Complaint in *Dickson* asserted claims under the federal FCA and 24 states' analogues. Such mass groupings of state FCA actions are increasingly common.[9]

The courts' "public policy" exception to *res judicata*—and the *Williams* line of cases on which it rests—creates a one-sided loophole in *qui tam* litigation, asymmetrically exempting only the state and federal governments from rules that serve the indispensable function of "reliev[ing] parties of the cost and vexation of multiple lawsuits, conserve[ing] judicial resources, * * * and * * * prevent[ing] inconsistent decisions." *Allen*, 449 U.S. at 94. Under these decisions, the government may deputize a relator to litigate on its behalf without expending any resources. It enjoys the lion's share of any recovery if the relator succeeds. But if the relator is

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minimum federal standards. See Cal. Gov't Code §§ 12650 *et seq.*; Colo. Rev. Stat. Ann. §§ 25.5-4-303.5 *et seq.*; Conn. Gen. Stat. §§ 4-274 *et seq.*; Ga. Code Ann. §§ 49-4-168 *et seq.*; Haw. Rev. Stat. Ann. §§ 661-21 *et seq.*; 740 Ill. Comp. Stat. Ann. 175/1 *et seq.*; Ind. Code Ann. §§ 5-11-5.7-1 *et seq.*; Iowa Code Ann. §§ 685.1 *et seq.*; Mass. Gen. Laws ch. 12, §§ 5A *et seq.*; Mont. Code Ann. §§ 17-8-401 *et seq.*; Nev. Rev. Stat. Ann. §§ 357.010 *et seq.*; N.Y. State Fin. Law §§ 187 *et seq.*; N.C. Gen. Stat. §§ 1-605 *et seq.*; Okla. Stat. tit. 63, §§ 5053 *et seq.*; R.I. Gen. Laws Ann. §§ 9-1.1-1 *et seq.*; Tenn. Code Ann. §§ 71-5-181 *et seq.*; Tex. Hum. Res. Code Ann. §§ 36.001 *et seq.*; Vt. Stat. Ann. tit. 32, §§ 630 *et seq.*; Va. Code Ann. §§ 8.01-216.1 *et seq.*; Wash. Rev. Code Ann. §§ 74.66.005 *et seq.*

[9] See, *e.g.*, *United States ex rel. Wallace* v. *Exactech, Inc.*, No. 2:18-CV-01010-LSC, 2020 WL 4500493, at *1 (N.D. Ala. Aug. 5, 2020) (federal FCA and 23 state analogues); see also *Mason* v. *Health Mgmt. Assocs., LLC*, 421 F. Supp. 3d 237, 241 (W.D.N.C. 2019) (federal FCA, seven state analogues); *United States ex rel. King* v. *Solvay S.A.*, 823 F. Supp 2d 472, 481 (S.D. Tex. 2011) (federal FCA and 23 state analogues); *United States ex rel. Bogart* v. *King Pharm.*, 414 F. Supp. 2d 540, 541 (E.D. Pa. 2006) (federal FCA and nearly a dozen state analogues).

unsuccessful, the government faces no risk and can go into court and pursue *the very same claims* against the very same defendants. Unsurprisingly, the states (like New Mexico) and the federal government are actively exploiting this loophole.[10]

Such lawsuits impose significant costs on litigants and the courts. Defending FCA lawsuits "requires a tremendous expenditure of time and energy," requiring defendants to "turn their focus from their businesses to defending against allegations of fraud." Todd J. Canni, *Who's Making False Claims, the* Qui Tam *Plaintiff or the Government Contractor?*, 37 Pub. Cont. L.J. 1, 11 n.66 (2007). Companies "spend billions each year" defending against such lawsuits. John T. Bentivoglio et al., *False Claims Act Investigations: Time for a New Approach?*, 3 Fin. Fraud L. Rep. 801, 801 (2011). Those costs are ultimately borne by the public in the form of higher prices for goods and services. Rich, 76 U. Cin. L. Rev. 1233, 1264 (2008) ("most non-intervened [*qui tam*] suits exact a net cost on the public").

And of course, these suits exact a heavy cost on the court systems that must accommodate *repeated* lawsuits—costs that are particularly unjustifiable because governments seek to relitigate *the very same claims* that courts have already expended significant resources to adjudicate. Again, this case is a perfect illustration. Nearly a decade after *Dickson* commenced (and nearly five years after that case was finally

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[10] See, *e.g.*, *KForce*, 2014 WL 5823460, at *6 n.2, *9 (dismissing and denying motion to amend complaint, but holding that dismissal was "without prejudice" to the government, who filed a statement of interest); *United States* v. *Organon USA, Inc.*, No. CV H-08-3314, 2013 WL 12142351, at *33-*34 (S.D. Tex. Feb. 1, 2013) (holding dismissal was with prejudice as to relator but without prejudice as to the government when government did not intervene but "filed statement to respond to arguments made by Defendants").

concluded), the State of New Mexico seeks to relitigate anew in state court claims arising from the same operative facts that the State "could have asserted" in *Dickson*. App. 28a.

The *res judicata* effect of federal judgments is a subject of special solicitude for this Court, which, it has emphasized, "has the last word on the claim-preclusive effect of *all* federal judgments." *Semtek Int'l*, 531 U.S. at 507. This Court's review is warranted.

IV. IN THE ALTERNATIVE, THIS COURT SHOULD VACATE THE JUDGMENT BELOW AND REMAND FOR FURTHER CONSIDERATION IN LIGHT OF *LUCKY BRAND DUNGAREES* AND *LOMAX*

Just last term, this Court issued two decisions that have clarified the *res judicata* effect of federal judgments. Because those decisions postdate the judgment under review, at a minimum, this Court should grant the petition, vacate the judgment below and remand for further consideration in light of those decisions. See *Wellons* v. *Hall*, 558 U.S. 220, 225 (2010) (*per curiam*) (vacatur and remand for further consideration in light of intervening precedent is warranted if there is "a reasonable probability that the decision below rests upon a premise that the lower court would reject if given the opportunity for further consideration").

On May 14, 2020, the day after oral argument in the New Mexico Supreme Court, this Court decided *Lucky Brand Dungarees, Inc.* v. *Marcel Fashions Group, Inc.*, 140 S. Ct. 1589 (2020), which clarified that federal courts' *res judicata* analysis employs the "transactional" approach to deciding whether two causes of actions are the same. *Id.* at 1594-1595. Thus, to the extent the Court of Appeals' application of its "public policy" exception rested on the district court's conclusion that the claims in *Dickson* and this case were not the same, it should be permitted to reassess that conclusion in light of the

holding in *Lucky Brand*, which applied the Restatement's "transactional" test, under which a judgment bars parties and privies from bringing later claims based on a "common nucleus of operative facts," "regardless of whether they were asserted or determined in the prior proceeding." *Ibid.*

What is more, on June 8, 2020, three days after the New Mexico Supreme Court quashed its writ of certiorari, this Court issued its unanimous decision in *Lomax*, which clarified the "old equitable principle" codified in Federal Rule of Civil Procedure 41(b), that when courts dismiss a complaint without specifying whether the dismissal is with or without prejudice, the default rule is that "courts [must] treat the dismissal 'as an adjudication on the merits'—meaning a dismissal with prejudice." 140 S. Ct. at 1725.[11] Because the New Mexico Court of Appeals' opinion below rests on its interpretation of a dismissal that did not "specify whether the order is with or without prejudice," *ibid.*, it should be given an opportunity to reconsider that decision in light of *Lomax*.

CONCLUSION

The petition for a writ of certiorari should be granted. In the alternative, this Court should grant the writ of certiorari, vacate the judgment below, and remand for

[11] Notably, during the pre-*Lomax* oral argument before the New Mexico Supreme Court, Justice C. Shannon Bacon raised a number of questions concerning whether dismissals under Rule 12(b)(6) were with prejudice under Rule 41(b). See Oral Argument at 7:26-10:21, *State ex rel. Balderas* v. *Bristol-Myers Squibb Co.*, No. S-1-SC-37430 (May 13, 2020), https://perma.cc/M3GD-NKBL.

further consideration in light of *Lucky Brand Dungarees* and *Lomax*.

Respectfully submitted.

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SEPTEMBER 2020

APPENDIX

APPENDIX A

IN THE COURT OF APPEALS OF THE STATE OF NEW MEXICO

Opinion Number: _____

Filing Date: October 24, 2018

NO. A-1-CA-36906

STATE OF NEW MEXICO ex rel. HECTOR BALDERAS, ATTORNEY GENERAL,

Plaintiff-Appellee,

v.

BRISTOL-MYERS SQUIBB COMPANY, SANOFI-AVENTIS U.S. LLC, SANOFI US SERVICES, INC. f/k/a SANOFI-AVENTIS U.S. INC., SANOFI-SYNTHELABO INC., and DOE DEFENDANTS 1 to 100,

Defendants-Appellants.

APPEAL FROM THE DISTRICT COURT OF SANTA FE COUNTY
Sarah M. Singleton, District Judge Pro Tem

* * * * *

OPINION

VANZI, Chief Judge.

{1} In this interlocutory appeal, we consider whether a federal district court's dismissal of qui tam claims for failure to state a claim bars the State from pursuing different claims arising from similar facts, where the State had not intervened in the qui tam action. We conclude that it does not and, therefore, affirm the denial of Defendants' motion to dismiss.

BACKGROUND

Qui Tam Actions

{2} In order to situate the facts leading to this appeal, we begin with an overview of qui tam actions generally and the relevant statutes that establish and govern them. "In a 'qui tam action,' a private plaintiff, . . . known as a 'relator,' brings suit on behalf of the government to recover a remedy for a harm done to the government." 36 Am. Jur. 2d *Forfeitures and Penalties §* 83 (2018) (footnotes omitted). "He or she pursues the government's claim against the defendant and asserts the injury in fact suffered by the government, which confers standing on the relator to bring the action as a representative of the [s]tate and as a partial assignee of the government's claim." *Id.* (footnotes omitted). A qui tam action arises only by statute, specifically authorizing a private party to sue on behalf of the government. *Id.* The federal False Claims Act (FCA) and state laws similar to it are typical qui tam statutes. *See United Seniors Ass'n v. Philip Morris USA,* 500 F.3d 19, 24 (1st Cir. 2007) (stating that the FCA is a "typical and commonly-invoked qui tam action").

The FCA and the New Mexico Medicaid False Claims Act

{3} "The [FCA] prohibits false or fraudulent claims for payment to the United States, and authorizes civil

actions to remedy such fraud to be brought by the Attorney General or by private individuals in the government's name." 32 Am. Jur. 2d *False Pretenses* § 85 (2018); 31 U.S.C. §§ 3729-3733 (2012). Under the FCA, "[t]he Attorney General diligently must investigate a violation of the false claims statute[,]" and "[i]f the Attorney General finds that a person has violated or is violating such statute, the Attorney General may bring a civil action against the person." 32 Am. Jur. 2d *False Pretenses* § 85; 31 U.S.C. § 3730(a). In addition, the FCA permits relators to "file qui tam civil actions on behalf of the United States for the making of a false claim against government funds." 32 Am. Jur. 2d *False Pretenses* § 85; 31 U.S.C. § 3730(b).

{4} Similarly, the New Mexico Medicaid False Claims Act (MFCA), NMSA 1978, §§ 27-14-1 to -15 (2004), provides for liability where a person presents "a claim for payment under the medicaid program knowing that such claim is false" or otherwise defrauds the state through the state medicaid program. Section 27-14-4. Like the FCA, the MFCA requires the Human Services Department (HSD) to investigate suspected violations and permits HSD to bring a civil action. Section 27-14-7(A). In addition, the MFCA contains a qui tam provision that permits "[a] private civil action [to] be brought by an affected person for a violation of the [MFCA] on behalf of the person bringing suit and for the state." Section 27-14-7(B).

{5} Both the FCA and MFCA require a relator to provide a copy of the complaint and written disclosure of material evidence possessed by the relator to the government so that the government may determine whether there is substantial evidence that a violation has occurred. 31 U.S.C. § 3730(b)(2); § 27-14-7(C). The complaint is sealed for at least sixty days to allow the government to undertake such an investigation. 31 U.S.C. § 3730(b)(2); § 27-14-7(C). Upon completion of the investigation, the government may either "proceed with the action, in which

case the action shall be conducted by the [g]overnment[,]" or decline to take over the action. 31 U.S.C. § 3730(b)(4); § 27-14-7(E). If the government declines to pursue the claims in the relator's complaint, "the person who initiated the action shall have the right to conduct the action." 31 U.S.C. § 3730(c)(3); § 27-14-8(D). Regardless of whether the government intervenes in the action, the relator may receive a portion of any ensuing recovery. 31 U.S.C. § 3730(d); § 27-14-9.

{6} The FCA and MFCA differ in that, under the MFCA, the relator may continue the action only "[i]f the department determined that there is substantial evidence that a violation of the [MFCA] has occurred" and that "[i]f the department determines that there is not substantial evidence that a violation has occurred, the complaint shall be dismissed." Section 27-14-7(C), (E)(2).

The First Suit: *In re Plavix Marketing, Sales Practice & Products Liability Litigation*

{7} The first suit at issue was initiated in March 2011 by relator Elisa Dickson (Relator), who filed a complaint alleging that Bristol-Myers Squibb Company, Sanofi-Aventis U.S., LLC; Sanofi-Aventis U.S., Inc.; and Sanofi-Synthelabo, Inc., (Defendants), manufacturers and marketers of the prescription drug Plavix, promoted Plavix in violation of the FCA and various states' similar fraud statutes, including New Mexico's MFCA. *See In re Plavix Mktg., Sales Practice & Prods. Liab. Litig. (No. II) v. Bristol-Myers Squibb Co.*, ___ F. Supp. 3d ___, 2017 WL 2780744, at *1-4 (D.N.J. 2017).[1] Pursuant to the provisions of the MFCA, Relator served New Mexico with "a copy of the complaint and written disclosure of substantially all material evidence and information [Relator] possesses."

[1] Relator filed the initial complaint in Illinois, but the suit was transferred to the United States District Court for the District of New Jersey to be part of the Plavix Multi-District Litigation. *Id.* at *2.

Section 27-14-7(C). New Mexico declined to intervene in Relator's suit and, therefore, declined to take over litigation of the MFCA claim. *In re Plavix Mktg.*, 2017 WL 2780744, at *2.

{8} Relator filed several amended complaints. *Id.* In August 2015, the federal district court dismissed the New Mexico MFCA claim, among others, for failure to state a claim for relief. *Id.* A year later, in August 2016, Relator filed a fourth amended complaint reasserting the MFCA claim, among others. *Id.* at *3. On Defendants' motion, the federal district court dismissed Relator's fourth amended complaint in June 2017. *Id.* at *1, *3. Relator did not appeal the dismissal or request permission to amend the complaint again. This final dismissal is central to Defendants' claim preclusion argument.

The Second Suit: *State of New Mexico ex rel. Hector Balderas, Attorney General v. Bristol-Myers Squibb, et al.*

{9} Shortly after Relator filed the fourth amended complaint in *In re Plavix Marketing,* but before its final dismissal, the New Mexico Attorney General (the State) brought the present action in the First Judicial District Court. The complaint alleges that "Defendants' false, deceptive, and unfair labeling and promotion of their prescription antiplatelet drug Plavix" violated the New Mexico Unfair Practices Act (UPA), NMSA 1978, §§ 57-12-1 to -26 (1967, as amended through 2009); the New Mexico Medicaid Fraud Act (MFA), NMSA 1978, §§ 30-44-1 to - 8 (1989, as amended through 2004); and the New Mexico Fraud Against Taxpayers Act (FATA), NMSA 1978, §§ 44-9-1 to -14 (2007, as amended through 2015), as well as common law and equitable causes of action. The complaint did not allege violations of the MFCA.

{10} Defendants moved to dismiss the State's complaint, arguing that the State had failed to state its claims.

They also maintained that the suit should be dismissed without prejudice or stayed pending resolution of the *In re Plavix Marketing* action and that the State was inappropriately splitting its claims. Without ruling on the substantive arguments in the motion, the state district court stayed the action pending the outcome of Defendants' motion to dismiss in *In re Plavix Marketing.* Once the federal district court dismissed Relator's fourth amended complaint, the state district court lifted the stay and ordered supplemental briefing on the impact of the dismissal of Relator's claims on the State's complaint and Defendants' motion to dismiss. In supplemental briefing, Defendants argued that the doctrine of claim preclusion bars the State's complaint. They also argued that, even if claim preclusion did not bar the State's claims in their entirety, the claims based on the MFA and FATA should be dismissed for failure to state a claim for the same reasons relied on by the federal district court.

{11} The state district court granted in part and denied in part Defendants' motion to dismiss for failure to state a claim. It found that the State's MFA claim failed as a matter of law and that the economic loss doctrine barred the State's negligence claim. It therefore dismissed those claims with prejudice. It found that the State had inadequately pleaded the UPA and equitable tolling claims but dismissed those claims without prejudice and ordered the State to file an amended complaint if it chose to rectify the deficiencies in the first complaint. The court found the remaining claims adequately pleaded. The State then filed its first amended complaint, which includes claims for violations of the UPA and FATA, as well as common law claims for fraud and unjust enrichment.

{12} In a separate order, the state district court denied Defendants' motion to dismiss the State's complaint on claim preclusion grounds. Although it stated that Relator's claims had been dismissed "with prejudice," it

found that "[claim preclusion] does not apply here because the causes of action are not the same in the two suits" and that "[R]elator in [*In re Plavix Marketing*] did not assert any of the claims the State asserts in this case, but rather only a single New Mexico [MFCA] claim." It also stated that "while [R]elator . . . stood in the shoes of the State of New Mexico for purposes of the New Mexico [MFCA] claim, [R]elator did not stand in the State's shoes for purposes of the claims asserted by the State here." Finally, the state district court concluded that "in a case such as this, where [R]elator's claims were dismissed based on a failure to comply with the heightened pleading requirements of [Federal Rule of Civil Procedure] 9(b), and not based on the merits of the claim, it would be inappropriate to bar the State's claims."

{13} However, the state district court also found that "[r]egarding the application of [claim preclusion] only," its order "(1) does not practically dispose of the merits of the action, (2) involves a controlling question of law as to which there is substantial ground for difference of opinion, and (3) an immediate appeal from this order or decision may materially advance the ultimate termination of the litigation." *See* NMSA 1978, § 39-3-4(A), (B) (1999) (providing for interlocutory appeal of district court orders pursuant to this Court's appellate jurisdiction). It therefore certified for interlocutory appeal the portion of the order pertaining to application of claim preclusion. This Court granted Defendants' application for interlocutory appeal. *See* Rule 12-203 NMRA (governing interlocutory appeals).

DISCUSSION

{14} The issue before the Court is whether the federal court's dismissal of Relator's MFCA claim precludes the State's claims for violations of the UPA and FATA, as well as common law fraud and unjust enrichment. We review such questions of law de novo. *Bank of N.Y. v.*

Romero, 2016-NMCA-091, ¶ 15, 382 P.3d 991. In addition, "[b]ecause the prior action was in federal court, federal law determines the preclusive effect of a federal judgment." *Moffat v. Branch,* 2005-NMCA-103, ¶ 11, 138 N.M. 224, 118 P.3d 732; *see* Restatement (Second) of Judgments § 87 (1982) ("Federal law determines the effects under the rules of [claim preclusion] of a judgment of a federal court."). However, this Court may rely on both federal and New Mexico law on claim preclusion because "[f]ederal law and New Mexico law are not divergent on claim preclusion doctrine, and both find the Restatement (Second) of Judgments . . . persuasive." *Moffat,* 2005-NMCA-103, ¶ 11.

General Claim Preclusion Law

{15} "[Claim preclusion] prevents a party or its privies from repeatedly suing another party for the same cause of action when the first suit involving the parties resulted in a final judgment on the merits." *Rosette, Inc. v. U.S. Dep't of the Interior,* 2007-NMCA-136, ¶ 33, 142 N.M. 717, 169 P.3d 704. Generally, the doctrine applies where "three elements are met: (1) a final judgment on the merits in an earlier action, (2) identity of parties or privies in the two suits, and (3) identity of the cause of action in both suits." *Id.* When these elements are satisfied, the defense of claim preclusion bars relitigation not only of claims actually brought by the plaintiff and its privies, but also claims that could have been brought in the first action. *Kirby v. Guardian Life Ins. Co. of Am.*, 2010-NMSC-014, ¶ 61, 148 N.M. 106, 231 P.3d 87.

{16} For claim preclusion to apply, the first suit must have ended in a "judgment on the merits." *Rosette, Inc.*, 2007-NMCA-136, ¶ 33. Generally, a dismissal for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6) is a "judgment on the merits" for purposes of claim preclusion. *Federated Dep't Stores, Inc. v. Moitie,*

452 U.S. 394, 399 n.3 (1981).[2] Although this general rule is often stated broadly, it is not without nuance. Because "[a] motion to dismiss for failure to state a claim under Rule 1-012(B)(6) . . . tests the legal sufficiency of the complaint, not the facts that support it[,]" *Wallis v. Smith,* 2001-NMCA-017, ¶ 6, 130 N.M. 214, 22 P.3d 682, the designation of such a dismissal as "on the merits" is something of a misnomer. In *Kirby,* the New Mexico Supreme Court explained that "[a] dismissal with prejudice is an adjudication on the merits only *to the extent that* when a claim has been dismissed with prejudice, the [final judgment on the merits] element of [claim preclusion] . . . will be presumed so as to bar a subsequent suit." 2010-NMSC-014, ¶ 66 (emphasis added). This is so because "[i]f this were otherwise, plaintiffs could simply ignore dismissals and file the same claim as many times as they wished, so long as the claim never progressed to a determination of the substantive issues." *Id.* Thus, the intent behind considering a Rule 12(b)(6) dismissal as "on the merits" is practical: to limit repetitive filings. *See Kirby,* 2010-NMSC-014, ¶ 66. Such a dismissal obviously does not involve "a judicial determination of" the actual merits. *See id.* ¶ 67. Conversely, "[t]he words 'without prejudice' when used in an order or decree generally indicate that there has been no resolution of the controversy on its merits and leave the issues in litigation open to another suit as if no action had ever been brought." *Bralley v. City of Albuquerque,* 1985-NMCA-043, ¶ 18, 102 N.M. 715, 699 P.2d 645.

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[2] "Because the language of Rule 1-012 [NMRA] closely parallels that of its federal counterpart, Rule 12 of the Federal Rules of Civil Procedure, we find federal authority interpreting Rule 12 . . . instructive." *Doe v. Roman Catholic Diocese of Boise, Inc.,* 1996-NMCA-057, ¶ 5, 121 N.M. 738, 918 P.2d 17. We also cite to Rule 1-012(B)(6) NMRA and Federal Rule of Civil Procedure 12(b)(6) interchangeably.

Defendants' Arguments

{**17**} Defendants contend that the elements of claim preclusion are met here. Defendants argue that the *In re Plavix Marketing* dismissal was "on the merits" because Relator either failed to plead the requisite materiality under *Universal Health Services, Inc. v. United States ex rel. Escobar*, ___ *U.S.*___, 136 S. Ct. 1989, 2001-03 (2016), or failed to allege conduct recognized as violative of the FCA. *See United States ex rel. Petratos v. Genentech Inc.,* 855 F.3d 481, 487 (3d Cir. 2017) ("A [FCA] violation includes four elements: falsity, causation, knowledge, and materiality."); *In re Plavix Mktg.,* 2017 WL 2780744, *8 (same). They also claim that the State was in privity with Relator because Relator represented the State's interests in the *In re Plavix Marketing* action. Finally, they argue that the State's claims "arise out of a common nucleus of operative facts" related to Defendants' marketing practices and, therefore, constitute the "same cause of action" as in *In re Plavix Marketing.* In sum, Defendants maintain that, as a privy to Relator, the State was required to bring all of its claims in *In re Plavix Marketing,* and having failed to do so, the State must be barred from bringing them in a different suit.

Claim Preclusion in the Context of Qui Tam Actions

{18} We first observe that, as a general proposition, "[i]f [the relator] had litigated a qui tam action to the gills and lost, neither another relator nor the [government] could start afresh." *United States ex rel. Lusby v. Rolls-Royce Corp.,* 570 F.3d 849, 853 (7th Cir. 2009). This is true because the relator sues on behalf of the government to vindicate the government's interests, and, although the government is not a named party to the relator's suit, it is a real party in interest. *United States ex rel. Eisenstein v. City of New* York, 556 U.S. 928, 934 (2009) (stating that the government, although a real party in interest, is not a "party" to a qui tam action).

{19} However, courts have also recognized that, under certain circumstances, the government's role in vindicating public interests militates against preclusion of its claims. *Cf.* Nathan D. Sturycz, *The King and I?: An Examination of the Interest Qui Tam Relators Represent and the Implications for Future False Claims Act Litigation,* 28 St. Louis U. Pub. L. Rev. 459, 462-63 (2009) (noting that even though "[i]n the non-FCA context, the concepts of preclusion would normally prevent duplicative litigation[, a]pplication of preclusion [in FCA cases] is muddled . . . by the distinction between the interests represented in a prior private cause of action and those represented in FCA litigation"). Thus, courts have repeatedly found that suits by or on behalf of the government should not be precluded by certain actions of a private party, even when that party acts as a qui tam relator. This is especially true when the first suit is dismissed for reasons unrelated to the merits of the claims.

{20} For example, federal courts have relied on the fact that a Rule 12(b)(6) dismissal is based only on the relator's complaint, not the factual bases underlying the allegations, to hold that such a dismissal does not preclude the government's claims when the government has not intervened. *See, e.g., United States ex rel. Williams v. Bell Helicopter Textron, Inc.,* 417 F.3d 450, 455-56 (5th Cir. 2005).

{21} In *Williams,* the district court dismissed the relator's FCA claims because the relator failed to plead them with sufficient particularity under Rules 12(b)(6) and (9)(b). *Williams,* 417 F.3d at 455. The district court dismissed the complaint with prejudice as to both the relator and the government, stating that it was "dismissing the claims against the government with prejudice because it believed 'the United States has had ample opportunity to participate in the prosecution of those claims if [it] had any notion that any of them has the slightest merit,' "

suggesting that the government's failure to intervene indicated that it found the claims meritless. *Id.*

{22} The United States Court of Appeals for the Fifth Circuit reversed and modified the dismissal to be without prejudice as to the government. *Id.* at 456. First, the court dismissed as "unreasonable" any speculation about the government's reasons for not intervening and the district court's inference that the government would have intervened if it found the relator's FCA claims "meritorious." *Id.* at 455. It observed that the FCA requires the Attorney General to conduct an investigation of the relator's allegations, but the FCA "does not require the government to proceed if its investigation yields a meritorious claim." *Id.* "Indeed, absent any obligation to the contrary, it may opt out for any number of reasons. For example, a decision not to intervene may 'not necessarily be an admission by the [government] that it has suffered no injury in fact, but rather the result of a cost-benefit analysis.' " *Id.* (alterations omitted) (quoting *United States ex rel. Berge v. Bd. of Trs. of the Univ. of Ala.*, 104 F.3d 1453, 1458 (4th Cir. 1997)). The court concluded, "[G]iven the Rule 9(b) deficiencies, the government may have determined that the costs associated with proceeding based on a poorly drafted complaint outweighed any anticipated benefits." *Williams*, 417 F.3d at 455.

{23} The *Williams* court then noted that a dismissal with prejudice as to the government would give private parties "perverse incentives" to file poorly drafted or improperly pleaded qui tam actions. *Id.* "By essentially requiring the government to intervene in order to avoid forfeiting any future claims against the defendant, private parties would have the added incentive to file FCA suits lacking in the required particularity, knowing full well that the government would be obligated to intervene and ultimately 'fill in the blanks' of the deficient complaint." *Id.* It went on to state that the district court's approach

would allow "a relator, in the most egregious of circumstances, to make sweeping allegations that, while true, he is unable to effectively litigate, but which nonetheless bind the government, via [claim preclusion], and prevent it from suing over those concerns at a later date when more information is available." *Id.* (internal quotation marks and citation omitted). It therefore concluded that the district court had abused its discretion by dismissing the complaint with prejudice as to the government. *Id.* at 456.

{24} Without deciding the preclusive effect of a Rule 12(b)(6) dismissal on future related actions, but relying on *Williams,* the Eleventh Circuit also modified a district court's dismissal for failure to state a claim to be without prejudice to the government. *Urquilla-Diaz v. Kaplan Univ.,* 780 F.3d 1039, 1057 (11th Cir. 2015). A number of federal district courts have also followed *Williams* and held that a dismissal of a relator's complaint for insufficient pleading should be without prejudice to the government. In each of these cases, the government had declined to intervene in the relators' actions. *See, e.g., United States v. KForce Gov't Sols., Inc.,* No. 8:13-cv-1517-T-36TBM, 2014 WL 5823460, at *6 n.2, *9 (M.D. Fla. Nov. 10, 2014) (dismissing an FCA complaint for failure to satisfy the Rule 9 pleading requirements and stating that dismissal is without prejudice to the government); *United States ex rel. Boros v. Health Mgmt. Assocs. (Health Mgmt. I),* No. 4:10-cv-10013-KMM, 2013 WL 12077816, at *1-2 (S.D. Fla. July 26, 2013) (clarifying that dismissal was without prejudice to the government after the relator's FCA complaint was dismissed for failure to state a claim); *United States ex rel. Banigan v. Organon USA, Inc.,* Civil Action H-08-3314, 2013 WL 12142351, at *34 (S.D. Tex. Feb. 1, 2013) (agreeing that "the dismissal [for inadequate pleadings] should be without prejudice to the [government] because it has no involvement in preparing the complaint" and stating that "if the [c]ourt dismisses [the

r]elators' complaint on insufficient pleading grounds, the dismissal would not preclude the government from bringing or continuing an action involving the same or similar claims"); *United States ex rel. Rostholder v. Omnicare, Inc.,* No. CCB-07-1283, 2012 WL 3399789, at *15 (D. Md. Aug. 14, 2012) (stating that "[t]he government's decision not to intervene . . . does not suggest that the government necessarily believed that no FCA case was viable . . . [and a]ccordingly, it would be inappropriate to dismiss with prejudice as to the [government] or *as to the states or localities* on whose behalf relator brought this claim" (emphasis added)), *aff'd,* 745 F.3d 694 (4th Cir. 2014). *But see Lusby,* 570 F.3d at 853 (stating that the district court erred in ordering a qui tam complaint dismissed with prejudice to the plaintiff and without prejudice to the government, but holding that judgment in a private suit did not bar a later qui tam action).

{25} Similarly, courts have dismissed a complaint with prejudice to the relator, but without prejudice to the government, where the relator failed to prosecute or acted improperly in litigation. *See, e.g., United States ex. rel. Prince v. Va. Res. Auth.,* 2014 WL 3405657, at *3 (W.D. Va. July 10, 2014) (failure to prosecute), *aff'd,* 593 Fed. App'x 230 (4th Cir. 2015); *United States ex rel. King v. DSE, Inc.,* No. 8:08-CV-2416-T-23EAJ, 2013 WL 610531, at *11 (M.D. Fla. Jan. 17, 2013) (litigation misconduct); *cf. United States ex rel. Vaughn v. United Biologics, L.L.C.,* ___ F.3d. ___, 2018 WL 5000074, at *5 (5th Cir. 2018) (stating that "when the case's outcome is decided by the relator's voluntary decision to quit, courts tend not to bind the [g]overnment to that decision automatically" and collecting cases).

{26} Although distinguishable on its *facts, State ex rel. Peterson v. Aramark Correctional Services, LLC,* 2014-NMCA-036, 321 P.3d 128, echoes the reasoning in *Williams.* In *Peterson,* this Court considered whether a

summary judgment in the plaintiffs personal injury suit barred the same plaintiff's later qui tam action against the same defendant. 2014-NMCA-036, ¶¶ 1-2. Holding that it did not, this Court noted that, as a qui tam relator, the plaintiff represented the state, rather than himself, and therefore, his capacity in the two suits was not the same and the "same parties or their privies" element of claim preclusion was not met. *Id.* ¶¶ 24, 33. In its analysis, this Court, like *Williams,* recognized that claim preclusion in the qui tam context could operate adverse to the public interest. *Peterson,* 2014-NMCA-036, ¶ 30. It stated that " 'it would be inappropriate to snuff out the government's interest [in the qui tam action] just because a potential relator thoughtlessly omitted a qui tam claim from a[n earlier] personal suit.' " *Id.* (alterations omitted) (quoting *Lusby,* 570 F.3d at 852). "[W]ere a personal lawsuit held to preclude a qui tam suit on claim preclusion grounds, the government would be incapable of vindicating its interest by bringing a new qui tam suit, either on its own or through another relator" because the government would be bound by the judgment in the personal lawsuit. *Id.*[3]

{27} Defendants argue that the *Williams* holding is inapposite for three reasons. Defendants first argue that the United States Supreme Court's decision in *Eisenstein* supersedes *Williams.* Defendants rely on the statement in *Eisenstein* that "the [government] is bound by the judgment in all FCA actions regardless of its participation in the case." 556 U.S. at 936. But the *Eisenstein* Court was not considering the issue here; rather, the issue

[3] Notably, although it was unnecessary for the *Peterson* Court to discuss this fact under the circumstances of that case, "the district court granted [the defendant's] motion for summary judgment, and dismissed, with prejudice, all claims brought on behalf of [the qui tam p]laintiff, stating, however, that its order did not prejudice the [s]tate's ability to bring a related action based on the same facts." *Id.* ¶ 20.

there was whether the government was a "party" to a privately initiated FCA action such that the private party could benefit from the longer period in which to appeal provided to the government under Federal Rule of Appellate Procedure 4(a)(1)(B). *Eisenstein,* 556 U.S. at 931. "The general rule is that cases are not authority for propositions not considered." *Sangre de Cristo Dev. Corp. v. City of Santa Fe,* 1972-NMSC-076, ¶ 23, 84 N.M. 343, 503 P.2d 323.

{28} In addition, the statement relied on by Defendants was a statement of the appellant's argument, not a statement of law by the Court. *See Eisenstein,* 556 U.S. at 936 *("*[*P*]*etitioner relies on the fact* that the [government] is bound by the judgment in all FCA actions regardless of its participation in the case." (emphasis added)). "[I]n light of *Eisenstein's* narrow holding—that the [g]overnment was not a 'party' for the purposes of [Rule] 4(a)(1)(B)—it would be inappropriate to interpret this passing observation so broadly." *Vaughn,* 2018 WL 5000074, at *6 (rejecting an argument that *Eisenstein* abrogated *Williams); accord USA ex rel. Mastej v. Health Mgmt. Assocs. (Health Mgmt. II),* No. 2:11-cv-89-FtM-29DNF, 2014 WL 12616929, at *2 (M.D. Fla. June 10, 2014); *Health Mgmt. I,* 2013 WL 12077816, at *1. Finally, as shown above, a number of federal courts have relied on *Williams* after *Eisenstein* was decided in 2009. *But see Lusby,* 570 F.3d at 853 (stating that *Eisenstein* foreclosed dismissal without prejudice as to the government).

{29} Defendants next argue that the policy considerations in *Williams* are inapposite because the MFCA "required New Mexico to determine whether there was substantial evidence of a violation . . . and to dismiss the claim if none existed." They argue that this "obligation means that no qui tam complaint brought under the [MFCA] should ever receive the State's approval to proceed if, like the [*Williams*] complaint, it is so facially deficient that it

lacks substantial evidentiary support." It is true that Section 27-14-7 requires that, when a claim is supported by substantial evidence, the state must either pursue the claim or permit the relator to pursue it. *See* § 27-14-7(E) (providing that if there is substantial evidence, the state "*shall:* (1) proceed with the action, in which case the action shall be conducted by the department; or (2) notify the court and the person who brought the action that it declines to take over the action" (emphasis added)). However, Defendants' argument conflates a determination of evidence supporting a claim with a determination of the adequacy of the relator's complaint. The state is required to determine only whether "there is substantial evidence that a violation has occurred," not whether the relator's complaint adequately alleges a violation. Section 27-14-7(C); *see Wallis,* 2001-NMCA-017, ¶ 6 (stating that "[a] motion to dismiss for failure to state a claim under Rule 1012(B)(6) . . . tests the legal sufficiency of the complaint, not the facts that support it"). To hold that the state is required to involve itself in the articulation of the relator's claims in the complaint is tantamount to requiring the state to intervene in the action. Such a result is contrary to the clear intent of the MFCA to deputize private parties to seek recovery on the state's behalf. *See Berge,* 104 F.3d at 1458 (stating that "the plain language of the [FCA] clearly anticipates that even after the [government] has 'diligently' investigated a violation . . . , the [g]overnment will not necessarily pursue all meritorious claims; otherwise there is little purpose to the qui tam provision permitting private attorneys general"); *see Vaughn,* 2018 WL 5000074, at *5 (citing *Williams* for the proposition that "the non-intervening [g]overnment should not be bound by the fate of an incompetent relator, lest it be forced to intervene in every action"); *see also* § 27-14-8(D) ("If the state elects not to proceed with the action, the person bringing the action shall have the right to conduct the action."); *cf. Williams,* 417 F.3d at 455 (stating that the

government might decline to intervene, even if there is evidence of a violation, because "the costs associated with proceeding based on a poorly drafted complaint [by the relator] outweighed any anticipated benefits").

{30} Finally, Defendants contend that *Williams* is factually distinguishable from the circumstances here. They argue that in *Williams,* the qui tam complaint was dismissed because it was "so deficient [under Rule 9(b)] that the court never reached the merits of the claim[,]" *Williams,* 417 F.3d at 456, whereas here Relator's claim was instead dismissed based on the "heightened pleading standard for materiality under the FCA," rather than the pleading requirements for fraud under Rule 9(b). *In re Plavix Mktg.,* 2017 WL 2780744, *10. They point out that the federal district court found that Relator had "pleaded herself out of court" by alleging facts that negated an essential element of an FCA claim. Thus, because Relator "could not plead the required element of 'materiality' as a matter of law[,]" the dismissal was on the merits.

{31} We do not read *Williams* as narrowly as Defendants. The *Williams* holding was not limited to the Rule 9(b) pleading standard. Instead, the core of the *Williams* holding is the failure to adequately plead an FCA claim under Rule 12(b)(6), regardless of the standard applied. *See Williams,* 417 F.3d at 453 (stating that the defendant "moved to dismiss under Rule 12(b)(6) for failure to state a claim because the complaint did not comply with the requirements of Rule 9(b)"). The reasoning for the holding was that the government should not be bound by the relator's weaknesses in pleading what might be a valid claim, whatever those weaknesses are. In other words, "[w]hy would Congress want [a poorly plead but meritorious] earlier suit to bar a later potentially successful suit that might result in a large recovery for the [g]overnment?" *Kellogg Brown & Root Servs., Inc. v. United States ex rel. Carter,* 135 S. Ct. 1970, 1979 (2015); *see id.*

(rejecting an argument that "a first-filed suit would bar all subsequent related suits even if that earlier suit was dismissed for a reason having nothing to do with the merits"). Hence, even if the *In re Plavix Marketing* dismissal was not based on Rule 9(b), an issue we need not decide, *Williams* would still apply here. *See KForce Gov't Sols.*, 2014 WL 5823460, at *9 (dismissing the relator's complaint where "the facts . . . plead . . . preclude a claim under the FCA" with prejudice, but without prejudice as to the government).

Dismissal of Relator's Qui Tam Action Does Not Bar the State's Claims

{32} The dismissal order in *In re Plavix Marketing* does not specify whether it is with or without prejudice to Relator or the government. *In re Plavix Mktg.*, 2017 WL 2780744, at *1, *23. Nevertheless, because the order did not provide for a fifth amendment and disposed of all of Relator's claims, we construe it as an adjudication on the merits as to Relator, consistent with the general rule that a dismissal under Rule 12(b)(6) is an adjudication on the merits for claim preclusion purposes. *Moitie,* 452 U.S. at 399 n.3 (stating that "[t]he dismissal for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6) is a judgment on the merits" (internal quotation marks and citation omitted)); *see Kirby,* 2010-NMSC-014, ¶ 66, 148 N.M. 106, 231 P.3d 87 (stating that this approach prevents repetitive suits); *Bralley,* 1985-NMCA-043, ¶ 14 ("An order dismissing a party's entire complaint without authorizing or specifying a definite time for leave to file an amended complaint, is a final order for purposes of appeal.").

{33} However, for the reasons stated in *Williams* and its progeny, we construe the order as without prejudice to the government. *Cf. Bralley,* 1985-NMCA-043, ¶ 18 (stating that "[t]he words 'without prejudice' when used in an order or decree generally indicate that there has been no

resolution of the controversy on its merits and leave the issues in litigation open to another suit as if no action had ever been brought"). Thus, as to the State, the federal district court's dismissal of Relator's fourth amended complaint is not a "final judgment on the merits" for claim preclusion purposes. "Because the claim preclusion doctrine does not bar a subsequent lawsuit unless all [of the claim preclusion] elements are met, we do not consider the parties' remaining claim preclusion arguments." *Peterson,* 2014-NMCA-036, ¶ 33.

CONCLUSION

{34} Consistent with federal FCA and claim preclusion law, we construe the *In re Plavix Marketing* dismissal as without prejudice to the State's claims, and, therefore, hold that the dismissal does not bar the State's present claims under the UPA and FATA, as well as common law claims for fraud and unjust enrichment. Accordingly, we affirm the state district court's denial of Defendants' motion to dismiss.

{35} **IT IS SO ORDERED.**

LINDA M. VANZI, Chief Judge

WE CONCUR:

J. MILES HANISEE, Judge

JULIE J. VARGAS, Judge

APPENDIX B

IN THE COURT OF APPEALS OF THE STATE OF NEW MEXICO

STATE OF NEW MEXICO ex rel. HECTOR BALDERAS, Attorney General,

Plaintiff-Appellee,

v.

BRISTOL-MYERS SQUIBB COMPANY, SANOFI-AVENTIS U.S. LLC, SANOFI U.S. SERVICES INC., formerly known as SANOFI-AVENTIS U.S. INC., SANOFI-SYNTHELABO INC., and DOE DEFENDANTS 1-100,

Defendants-Appellants.

No. A-1-CA-36906

ORDER DENYING MOTION FOR REHEARING

This matter is before the Court on Appellants' motion for rehearing and Appellee's response thereto. The original panel has considered the motion and response.

THE COURT ORDERS THAT the motion is **DENIED**.

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LINDA M. VANZI, Chief Judge

APPENDIX C

IN THE SUPREME COURT OF THE STATE OF NEW MEXICO

March 11, 2019

NO. S-1-SC-37430

STATE OF NEW MEXICO, ex rel. HECTOR BALDERAS, ATTORNEY GENERAL,

Plaintiff-Respondent,

v.

BRISTOL-MYERS SQUIBB COMPANY, SANOFI-AVENTIS U.S. LLC, SANOFI U.S. SERVICES, INC. f/k/a SANOFI-AVENTIS U.S. INC., SANOFI-SYNTHELABO INC., and DOE DEFENDANTS 1-100,

Defendants-Petitioners.

ORDER

WHEREAS, this matter came on for consideration by the Court upon petition for writ of certiorari and response filed pursuant to Rule 12-502 NMRA, petitioners' motion for leave to file a reply, and response thereto, and the Court having considered the foregoing and being sufficiently advised, Chief Justice Judith K. Nakamura,

Justice Barbara J. Vigil, Justice Michael E. Vigil, Justice C. Shannon Bacon, and Justice David K. Thomson concurring;

NOW, THEREFORE, IT IS ORDERED that the petition is GRANTED and a writ of certiorari shall issue to the New Mexico Court of Appeals;

IT IS FURTHER ORDERED that the petition is GRANTED on all questions as presented in the petition, and a subsequent order shall be entered setting forth instructions regarding a briefing schedule, if any; and

IT IS FURTHER ORDERED that the motion for leave to file a reply is DENIED.

IT IS SO ORDERED.

[seal]

WITNESS, the Honorable Judith K. Nakamura, Chief Justice of the Supreme Court of the State of New Mexico, and the seal of said Court this 11th day of March, 2019.

Joey D. Moya, Chief Clerk of the Supreme Court of the State of New Mexico

APPENDIX D

IN THE SUPREME COURT OF THE STATE OF NEW MEXICO

June 05, 2020

NO. S-1-SC-37430

STATE OF NEW MEXICO, ex rel. HECTOR BALDERAS, ATTORNEY GENERAL,

Plaintiff-Respondent,

v.

BRISTOL-MYERS SQUIBB COMPANY, SANOFI-AVENTIS U.S. LLC, SANOFI US SERVICES, INC. f/k/a SANOFI-AVENTIS U.S. INC., SANOFI-SYNTHELABO INC., and DOE DEFENDANTS 1-100,

Defendants-Petitioners.

ORDER

WHEREAS, this matter came on for consideration upon petition for writ of certiorari filed pursuant to Rule 12-502 NMRA, and the Court having considered said petition and being sufficiently advised, issued its writ of certiorari on March 11, 2019;

WHEREAS, the parties filed briefs and subsequently presented oral arguments on May 13, 2020; and

WHEREAS, having considered the foregoing, the judgment of the Court is that the writ shall be quashed as improvidently granted, Justice Barbara J. Vigil, Justice Michael E. Vigil, Justice C. Shannon Bacon, and Justice David K. Thomson concurring; Chief Justice Judith K. Nakamura not participating;

NOW, THEREFORE, IT IS ORDERED that the writ of certiorari issued on March 11, 2019, is QUASHED; and

IT IS FURTHER ORDERED that upon issuance of mandate in accordance with Rule 12-402(B) NMRA the record proper, transcript of proceedings, and any exhibits shall be returned to the New Mexico Court of Appeals.

IT IS SO ORDERED.

[seal]

WITNESS, the Honorable Judith K. Nakamura, Chief Justice of the Supreme Court of the State of New Mexico, and the seal of said Court this 5th day of June, 2020.

APPENDIX E

STATE OF NEW MEXICO
COUNTY OF SANTA FE
FIRST JUDICIAL DISTRICT COURT

STATE OF NEW MEXICO, *ex rel.* HECTOR BALDERAS, ATTORNEY GENERAL,

Plaintiff,

vs.

BRISTOL-MYERS SQUIBB COMPANY, SANOFI-AVENTIS U.S. LLC SANOFI US SERVICES INC., formerly known as SANOFI-AVENTIS U.S. INC., SANOFI-SYNTHELABO INC., and DOE DEFENDANTS 1 to 100,

Defendants.

No. D-101-CV-2016-02176

ORDER DENYING DEFENDANTS' MOTION TO DISMISS BASED ON RES JUDICATA AND CERTIFICATION OF THE ISSUE FOR INTERLOCUTORY APPEAL

THIS MATTER, having come before the Court on Defendants' Motion to Dismiss based on *res judicata*, and **THIS COURT**, having reviewed the briefing on the Motion, including supplemental briefing, and having heard oral argument on November 3, 2017, **FINDS**:

1. In September 2016, the State of New Mexico brought this action against Defendants, manufacturers of

the prescription drug Plavix. The State alleges that Defendants engaged in false, deceptive, and unfair marketing of Plavix as more fully alleged in the State's complaint, and asserts causes of action for violations of the New Mexico Unfair Practices Act, NMSA 1978, Sections 57-12-1 *et seq.*, the New Mexico Medicaid Fraud Act, NMSA 1978, Sections 30-44-1, *et seq.*, and the New Mexico Fraud Against Taxpayers Act ("FATA"), NMSA 1978, Sections 44-9-1 *et seq.*, as well as common law claims for fraud, negligence, and unjust enrichment.

2. This Court previously stayed this action pending resolution of another lawsuit against Defendants in New Jersey federal court, *United States ex rel. Dickson v. Bristol Myers Squibb Co.*, MDL No. 13-2418, No. 13-1039 (D.N.J.) ("*Dickson*"). *Dickson* was a federal False Claims Act ("FCA") *qui tam* action brought by a relator on behalf of the federal government and multiple states, including the State of New Mexico, alleging that Defendants fraudulently promoted Plavix. On behalf of the State of New Mexico, the relator asserted a single cause of action for violation of the New Mexico Medicaid False Claims Act, NMSA, Sections 27-14-1 *et seq.*, a cause of action not asserted by the State in this action.

3. On June 27, 2017, the federal court in *Dickson* dismissed the relator's Fourth Amended Complaint with prejudice at the pleading stage, including the New Mexico Medicaid False Claims Act claim brought on behalf of the State of New Mexico. The court found that the relator failed to plead the element of materiality required to state a claim under, *inter alia*, the New Mexico Medicaid False Claims Act. The court explained that "the imposition by the Supreme Court in [*Universal Health Servs., Inc. v. United States and Massachusetts, ex rel. Escobar*, 136 S. Ct. 1989, 2001 (2016)] of a heightened pleading standard for materiality under the FCA to be dispositive of

Relator's allegations in the [Fourth Amended Complaint]." No appeal was taken from this order of dismissal in *Dickson*.

4. In August 2017, Defendants moved to dismiss this action, arguing that, under the *res judicata* doctrine, the State's claims are barred by the dismissal in *Dickson*. *Res judicata* applies when (1) there was a final judgment in an earlier action, (2) the earlier judgment was on the merits, (3) the parties in the two suits are the same, and (4) the cause of action is the same in both suits.

5. This Court finds that *res judicata* does not apply here because the causes of action are not the same in the two suits. The relator in *Dickson* did not assert any of the claims the State asserts in this case, but rather only a single New Mexico Medicaid False Claims Act claim. And, with the exception of the State's FATA claim here, the relator could not have asserted the claims the State asserts here because the relator lacked authority to do so. If the State had intervened in *Dickson*, the State could have asserted those claims, but the State elected not to intervene. While the relator could have asserted the State's FATA claim in *Dickson*, she was not required to do so, and therefore *res judicata* does not bar the State from asserting its FATA claim here.

6. Thus, while the relator in the *Dickson* case stood in the shoes of the State of New Mexico for purposes of the New Mexico Medical False Claims Act claim, the relator did not stand in the State's shoes for purposes of the claims asserted by the State here.

7. Furthermore, in a case such as this, where the relator's claims were dismissed based on a failure to comply with the heightened pleading requirements of Rule 9(b), and not based on the merits of the claim, it would be inappropriate to bar the State's claims.

8. The Court makes no ruling on whether the dismissal of the *Dickson* case would preclude a New Mexico Medicaid False Claims Act claim here.

9. Based on the foregoing, as well as the legal arguments and authorities presented in the parties' briefs and by counsel during oral argument, Defendants' Motion to Dismiss on the basis of *res judicata* is **DENIED**.

10. Regarding the application of *res judicata* only, the Court **FINDS** that this Order: (1) does not practically dispose of the merits of the action, (2) involves a controlling question of law as to which there is substantial ground for difference of opinion, and (3) an immediate appeal from this order or decision may materially advance the ultimate termination of the litigation. NMSA 1978 § 39-3-4.

11. Therefore, the portion of this Order regarding the application of *res judicata* is hereby Certified for interlocutory appeal.

IT IS SO ORDERED.

_____

Sarah M. Singleton, Judge Pro Tem,
Sitting by Designation

* * * * *

APPENDIX F

STATE OF NEW MEXICO
COUNTY OF SANTA FE
FIRST JUDICIAL DISTRICT COURT

STATE OF NEW MEXICO, *ex rel.* HECTOR BALDERAS, ATTORNEY GENERAL,
Plaintiff,
vs.
BRISTOL-MYERS SQUIBB COMPANY, SANOFI-AVENTIS U.S. LLC, SANOFI US SERVICES INC., formerly known as SANOFI-AVENTIS U.S. INC., SANOFI-SYNTHELABO INC., and DOE DEFENDANTS 1 to 100,
Defendants.

No. D-101-CV-2016-02176
Hon. Sarah Singleton

PLAINTIFF'S FIRST AMENDED COMPLAINT FOR DECLARATORY RELIEF, DAMAGES, RESTITUTION AND CIVIL PENALTIES

1. Plaintiff, the State of New Mexico (hereinafter "the State"), by and through its Attorney General, Hector Balderas, hereby brings this action against Defendants Bristol-Myers Squibb Company ("BMS"), Sanofi-Aventis U.S. LLC, Sanofi US Services Inc., formerly known as Sanofi-Aventis U.S. Inc., and Sanofi-Synthelabo Inc. (collectively, "Defendants") and alleges, upon information and belief, as follows:

2. This action arises from Defendants' false, deceptive, and unfair labeling and promotion of their prescription antiplatelet drug Plavix (clopidogrel bisulfate), which

are actionable under the New Mexico Unfair Practices Act, NMSA 1978, Sections 57-12-1 *et seq.*, and the New Mexico Fraud Against Taxpayers Act, NMSA 1978, Sections 44-9-1 *et seq*., and for other common law and equitable causes of action stated herein by the New Mexico Attorney General in the exercise of his statutory powers.

3. Beginning in March 1998, until the present, Defendants have engaged in a false, deceptive, and unfair marketing strategy designed to increase revenues from Plavix. Since at least March 1998, Defendants knew or should have known that Plavix has diminished or no effect on a substantial and significant percentage of the patient population and that those patients for whom Plavix would not work could be identified through a simple genetic test. Yet, Defendants failed to disclose that negative efficacy information because it would adversely affect the number of Plavix prescriptions written and, thus, sales and revenues. For such patients, Plavix does not prevent heart attacks, strokes, or vascular death, and it presents a considerable risk of gastrointestinal bleeding and other complications. After scientists began to learn that Plavix has diminished or no effect on a significant percentage of the patient population, Defendants sought to protect Plavix's sales and increase revenues by marketing higher (and more expensive) doses of Plavix for such patients, placing them at even greater risk, while triggering substantially higher pharmacy costs incurred by government payors.

4. Since March 1998, Defendants have also falsely and misleadingly sought to replace aspirin with Plavix, which costs one hundred times more than aspirin, for treatment of patients at risk for ischemic events. Defendants ignored, concealed, and minimized clinical trial data and other information showing that Plavix is only as effective as – or in some cases even less effective than – aspirin in treating such patients, and that Plavix has a higher chance of causing gastrointestinal bleeding and other

complications. Despite that information, Defendants falsely and misleadingly marketed Plavix as being more effective and safer than aspirin. Defendants also falsely and misleadingly marketed Plavix as being more effective and safer than other competitor drugs. In 2010, the American Stroke Association ("ASA") confirmed what Defendants knew or by the exercise of reasonable care should have known at all relevant times: "No studies have compared clopidogrel [Plavix] with placebo, and studies comparing it with other antiplatelet agents [including aspirin] have not clearly established that it is superior or even equivalent to any one of them."

5. In addition, Defendants falsely, deceptively, and unfairly marketed Plavix as effective and safe for uses for which the drug had not been shown to be effective or safe. Defendants also, through deliberate deception or otherwise, knowingly caused false claims to be submitted to the State for reimbursement in connection with prescriptions for a drug that was not medically necessary and was not cost-effective.

6. Defendants' aggressive marketing strategy, combined with Defendants' successful cover-up of mounting adverse efficacy and safety evidence, produced billions of dollars in profits for Defendants. Plavix's sales in the United States peaked at $6.62 billion in 2011.

7. Plaintiff seeks to recover the costs of Plavix and the costs of Plavix-related illnesses, including, but not limited to, expenditures for:

a. Medical assistance provided under New Mexico's Medicaid Program pursuant to the Public Assistance Act, N.M. STAT. ANN. § 27-2-1 *et seq.*;

b. Public employees' health insurance coverage costs pursuant to the Group Benefits Act, N.M. STAT. ANN. § 10-7B-6;

c. Retired public employees' group insurance costs from the Retiree Health Care Fund, pursuant to the Retiree Health Care Act, N.M. STAT. ANN. § 10-7C-8;

d. Public employees and school board retirees' group health insurance costs from the Public School Insurance Fund, pursuant to the Public School Insurance Authority Act, N.M. STAT. ANN. § 22-2-6.6 and/or N.M. STAT. ANN. § 22-29-1; and

e. Any other expenditures by the New Mexico Human Services Department, the New Mexico Department of Health, the New Mexico Department of Corrections, the Risk Management Division of the General Services Department, the Retiree Health Care Authority and/or the Public Schools Insurance Authority.

f. Patients who have received Plavix prescriptions and/or treatment for Plavix-related illnesses in connection with expenditures made by the above-described State programs, agencies and/or departments are hereinafter collectively referred to as "State of New Mexico participants".

8. The State brings this action exclusively under the laws of the State of New Mexico. No federal claims are being asserted, and to the extent that any claim or factual assertion set forth herein may be construed to have stated any claim under federal law, such claim is expressly and undeniably disavowed and disclaimed by the State.

9. Nor does the State bring this action on behalf of a class or any group of persons that can be construed as a class. Nor does the State bring this as a mass action or state its claims and causes of action in any way that can be construed as a mass action. The claims asserted herein are brought solely by the State and are wholly independent of any claims that individual users of Plavix may have against Defendants.

THE PARTIES

10. Plaintiff, the State of New Mexico, is a body politic created by the Constitution and laws of the State of New Mexico, and as such is not a citizen of any State.

11. Attorney General Hector Balderas is the present Attorney General of the State of New Mexico. Attorney General Hector Balderas is acting pursuant to his authority under, *inter alia*, NMSA 1978, Sections 8-5-1 *et seq*., the New Mexico Unfair Practices Act, NMSA 1978, Sections 57-12-1 *et seq.*, and the New Mexico Fraud Against Taxpayers Act, NMSA 1978, Sections 44-9-1 *et seq*.

12. Upon information and belief, Defendant Bristol-Myers Squibb Company ("BMS") is a Delaware corporation with its principal corporate offices at 345 Park Avenue, New York, New York 10154 and facilities throughout the State of New Jersey. Plaintiff is informed and believes, and based thereupon alleges, that at all relevant times BMS has manufactured, advertised, labeled, marketed, promoted, sold, and distributed Plavix in the United States, and has, directly or through and in concert with its co-Defendants, systematically and continuously advertised, marketed, promoted, sold, and/or distributed Plavix within the State of New Mexico. BMS is registered to do business in New Mexico.

13. Upon information and belief, Defendant Sanofi-Aventis U.S. LLC is a Delaware limited liability company with headquarters and research facilities located at 55 Corporate Drive, Bridgewater, New Jersey 08807. Plaintiff is informed and believes, and based thereupon alleges, that at all relevant times Sanofi-Aventis U.S. LLC has engaged in the business of manufacturing, developing, advertising, labeling, marketing, promoting, selling, and/or distributing Plavix in the United States, and has, directly or through and in concert with its co-Defendants, systematically and continuously advertised, marketed,

promoted, sold, and/or distributed Plavix within the State of New Mexico.

14. Upon information and belief, Defendant Sanofi US Services Inc., formerly known as Sanofi-Aventis U.S. Inc., is a Delaware corporation with offices located at 55 Corporate Drive, Bridgewater, New Jersey 08807. Plaintiff is informed and believes, and based thereupon alleges, that at all relevant times Defendant Sanofi US Services Inc. f/k/a Sanofi-Aventis U.S., Inc. has engaged in the business of manufacturing, developing, advertising, labeling, marketing, promoting, selling, and/or distributing Plavix in the United States, and has, directly or through and in concert with its co-Defendants, systematically and continuously advertised, marketed, promoted, sold, and/or distributed Plavix within the State of New Mexico.

15. Upon information and belief, Defendant Sanofi-Synthelabo Inc. is a Delaware corporation. Plaintiff is informed and believes, and based thereupon alleges, that at all relevant times Sanofi-Synthelabo Inc. has engaged in the business of manufacturing, developing, advertising, labeling, marketing, promoting, selling, and/or distributing Plavix in the United States, and has, directly or through and in concert with its co-Defendants, systematically and continuously advertised, marketed, promoted, sold, and/or distributed Plavix within the State of New Mexico.

16. Defendants Sanofi-Aventis U.S. LLC, Sanofi US Services Inc., formerly known as Sanofi-Aventis U.S., Inc., and Sanofi-Synthelabo Inc. are collectively referred to as "Sanofi" in this Complaint.

17. At all relevant times, Defendants have packaged, distributed, supplied, sold, placed into the stream of commerce, labeled, described, marketed, advertised, promoted, and purported to warn or purported to inform users regarding the benefits and risks associated with the use of the prescription drug Plavix.

18. DOE DEFENDANTS 1 to 100 are sued herein under fictitious names for the reason that after diligent and good faith efforts their names, identities, and capacities, whether individual, corporate, associate, or otherwise, are presently unknown to Plaintiff. Plaintiff will make the names or identities of said Defendants known to the Court after the same have been ascertained. Plaintiff is informed and believes, and based thereupon alleges, that each of the Defendants designated herein as a DOE DEFENDANT has taken part in and participated with, and/or aided and abetted, some or all of the other Defendants in some or all of the matters referred to herein and has been in some manner responsible for some or all of the deceptive and unfair practices and violations of New Mexico's Unfair Practices Act and Fraud Against Taxpayers Act, and all common law violations alleged herein.

19. Plaintiff is informed and believes, and based thereupon alleges, that at all relevant times, each Defendant has occupied agency, employment, joint venture, or other relationships with each of the other named and DOE DEFENDANTS; that at all times herein mentioned each Defendant has acted within the course and scope of said agency, employment, joint venture, and/or other relationship; that each other Defendant has ratified, consented to, and approved the acts of its agents, employees, joint venturers, and representatives; and that each has actively participated in, aided and abetted, or assisted one another in the commission of the wrongdoing alleged in this Complaint.

20. At all relevant times, Defendants, and each of them, have engaged in the business of, or were successors in interest to, entities engaged in the business of researching, licensing, designing, formulating, developing, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, advertising, distributing, and/or

selling the prescription drug Plavix as an antiplatelet medication to individuals and entities in the State of New Mexico, including the City and County of Santa Fe, New Mexico.

21. At all relevant times, Defendants have been authorized to do business within the State of New Mexico and have in fact sold and supplied Plavix to individuals and entities located within every county of the State of New Mexico.

JURISDICTION AND VENUE

22. The courts of New Mexico have jurisdiction over the subject matter of this action pursuant to, *inter alia*, Article VI, Section 13 of the New Mexico Constitution.

23. This Court has personal jurisdiction over Defendants because Defendants do business in New Mexico and/or have the requisite minimum contacts with New Mexico necessary to constitutionally permit the Court to exercise jurisdiction with such jurisdiction also being within the contemplation of the New Mexico "long arm" statute, NMSA 1978, Section 38-1-16.

24. Defendants did distribute, supply, market, sell, promote, and advertise Plavix and otherwise commit the wrongful acts and omissions described herein in New Mexico and specifically in Santa Fe County.

25. Venue is proper in Santa Fe County pursuant to NMSA 1978, Section 38-3-1 because: (1) the Attorney General resides in Santa Fe County, New Mexico; and (2) the causes of action alleged herein originated in part in Santa Fe County. Venue is also proper in Santa Fe County pursuant to NMSA 1978, Section 57-12-8 because Defendants have used methods, acts or practices in Santa Fe County which are unlawful under the Unfair Practices Act.

26. The instant Complaint does not confer diversity jurisdiction upon the federal courts pursuant to 28 U.S.C.

§ 1332. Likewise, federal question subject matter jurisdiction pursuant to 28 U.S.C. § 1331 is not invoked by the instant Complaint, as it sets forth herein exclusively state law claims against Defendants. Nowhere herein does Plaintiff plead, expressly or implicitly, any cause of action or request any remedy which is founded upon federal law. The issues presented in the allegations of the instant Complaint do not implicate significant federal issues; do not turn on the substantial federal interpretation of federal law; nor do they raise a substantial federal question. Indeed, Plaintiff expressly avers that the only causes of action claimed, and the only remedies sought herein, are for those founded upon the statutory, common, and decisional laws of the State of New Mexico. Further, assertion of federal jurisdiction over the claims made herein would improperly disturb the congressionally approved balance of federal and state responsibilities. Neither this case, nor any issue in this case has any effect on the federal system as a whole. Accordingly, any improvident and dilatory attempt by Defendant to remove this case to federal court would be without a reasonable legal basis in fact or law.

FACTUAL BACKGROUND

I. DEFENDANTS' FALSE, DECEPTIVE, AND UNFAIR MARKETING OF PLAVIX

27. Plavix is an oral tablet formulation of clopidogrel bisulfate manufactured by BMS and jointly marketed in the United States by Defendants. All marketing and pricing decisions for Plavix have been made and implemented jointly by Defendants. Since March 17, 1998, Plavix has been exclusively marketed in the United States by Defendants under the registered trademark "Plavix®."

28. Plavix was first approved by the FDA on November 17, 1997 for the reduction of atherosclerotic events, *i.e.*, myocardial infarction (also known as a heart attack),

stroke, and vascular death, in patients with atherosclerosis documented by recent stroke, recent myocardial infarction, or established peripheral arterial disease ("PAD"). On February 27, 2002, the FDA approved Plavix for the treatment of patients with a certain type of Acute Coronary Syndrome (unstable angina/non-ST-elevation myocardial infarction), also known as "NSTEMI." On August 17, 2006, the FDA approved Plavix for the treatment of patients with another type of Acute Coronary Syndrome (ST-elevation myocardial infarction), also known as "STEMI."

A. Failure to Disclose Plavix's Diminished Effectiveness in a Significant Percentage of the Patient Population

29. On March 25, 2010, Defendants added a black box warning to Plavix's label that states that Plavix does not become effective until it is metabolized into its active form by the CYP2C19 liver enzyme. Individuals with particular CYP2C19 genotypes are CYP2C19 poor metabolizers. The black box warning added in March 2010 cautions that Plavix has diminished effectiveness in patients who are CYP2C19 poor metabolizers, and recommends alternative therapies in such patients.

30. It is believed that a significant percentage of the patient population in New Mexico consists of CYP2C19 poor metabolizers.

31. The black box warning added in March 2010 also states that patients who are CYP2C19 poor metabolizers treated with Plavix have higher cardiovascular event rates than patients with normal CYP2C19 function. The black box warning further states that tests are available to identify a patient's CYP2C19 genotype and aid in determining prescribing decisions, and to consider alternative treatment in patients identified as CYP2C19 poor metabolizers.

32. Plaintiff is informed and believes, and based thereupon alleges, that since at least March 1998, 12 years before the black box warning was added, Defendants knew or by the exercise of reasonable care should have known that Plavix has diminished or no effect on patients who are CYP2C19 poor metabolizers. Upon information and belief, Defendants, however, failed to disclose that information in order to protect Plavix's sales and revenues.

33. Plaintiff is also informed and believes, and based thereupon alleges, that since at least 2003, Defendants knew or by the exercise of reasonable care should have known that Plavix has diminished or no effect on patients who are also taking drugs that are CYP2C19 inhibitors. Upon information and belief, Defendants, however, failed to disclose that information in order to protect Plavix's sales and revenues.

34. Plaintiff is further informed and believes, and based thereupon alleges, that when information about Plavix's lack or utter absence of efficacy in patients who are poor CYP2C19 metabolizers became known in the scientific community through other channels, Defendants attempted to undermine that information and protect Plavix's sales and increase its revenues by urging physicians to prescribe higher (and more expensive) doses of Plavix to such patients, putting them at a higher risk of gastrointestinal bleeding and other complications associated with Plavix.

35. Scientific literature available years before Defendants submitted Plavix's new drug application ("NDA") in 1997 described the genetic variations of the CYP2C19 enzyme that cause it to metabolize poorly in a significant percentage of the patient population, and the prevalence of those genetic variations in certain populations (e.g., Caucasian, African, and Asian). Such literature also described the effect of those genetic variations on drugs dependent on the CYP2C19 enzyme. An article

in the Journal of Biological Chemistry concluded in 1994 that a defect in the CYP2C19 enzyme interfered with metabolization of numerous drugs. However, and importantly, the article's authors stated that they were able to test for the defect through a simple genetic test.

36. When Defendants submitted their NDA for Plavix in 1997, they relied on a very small data set and claimed not to understand exactly how the drug was metabolized. However, Defendants indicated that they knew that Plavix was metabolized in the liver, and that the CYP2C19, CYP2B6, and CYP3A4 enzymes of the cytochrome P450 system were principally involved.

37. In 2002 and 2003, published studies distinguished between responders and non-responders to Plavix. In 2002, individual variations in responsiveness to Plavix were reported.

38. Several articles published in 2004 and 2005 confirmed that Plavix has diminished or no effect on a significant portion of Plavix patients because they metabolize the drug poorly.

39. In 2005, the Journal of the American College of Cardiology published the results of a study, which Defendants sponsored, examining the effectiveness of 544 individuals to Plavix, concluding that "there is a very large range of responsiveness to ex vivo testing" in patients using Plavix, and that "it is likely that a small but significant portion of patients are receiving inadequate protection from thrombotic events despite currently standard antiplatelet therapy, whereas a similar proportion may be at higher risk for bleeding complications."

40. In February 2006, the Journal of the American College of Cardiology published an abstract concluding that patients with a CYP2C19*2 allele are associated with a diminished response to Plavix, which may also explain

why patients had previously reported variability in response to the drug.

41. In June 2006, the American Society of Hematology published the results of a study in an article stating that "pharmacodynamic response to [Plavix] varies widely from subject to subject, and about 25% of patients treated with standard [Plavix] doses display low ex vivo inhibition of ADP-induced platelet aggregation." The authors concluded that "response to [Plavix] was strongly influenced by the CYP2C19 genotypic status."

42. In January 2009, a study in the New England Journal of Medicine concluded that among persons treated with Plavix, "carriers of a reduced-function CYP2C19 allele had significantly lower levels of the active metabolite of [Plavix], diminished platelet inhibition, and a higher rate of major adverse cardiovascular events, including stent thrombosis, than did noncarriers." That study found that approximately 30% of the study participants had at least one reduced-function CYP2C19 allele. A different study published in 2009 estimated that the presence of such an allele is even more prevalent in African-American and Asian populations.

43. Plaintiff is informed and believes, and based thereupon alleges, that Defendants have known or should have known of additional information regarding Plavix's diminished or complete lack of effectiveness in many patients since at least March 1998.

44. There is no indication that Defendants brought any of the foregoing information about Plavix's lack of effectiveness to the public's attention until after the FDA notified Defendants in March 2009 of "new safety information" that should be included in Plavix's labeling; Defendants knew or should have known of information regarding Plavix's diminished or complete lack of effectiveness in many patients for over a decade.

45. Plaintiff is further informed and believes, and based thereupon alleges, that Defendants have misrepresented and failed to adequately disclose that Plavix is less effective in elderly patients than in younger patients, which Defendants knew or in the exercise of reasonable care should have known since at least August 2001.

46. By making statements about Plavix's efficacy and/or safety without disclosing information regarding Plavix's diminished or complete lack of effectiveness in many patients, Defendants made false and misleading statements and representations when marketing the drug, including in its labeling, sales materials, and other promotional materials and efforts.

47. Upon information and belief, at all relevant times, Defendants made the foregoing statements and omissions concerning Plavix's efficacy and safety to healthcare providers and the general public throughout the nation, including New Mexico.

B. False, Deceptive, and Unfair Superiority Claims

48. Plaintiff is informed and believes, and based thereupon alleges, that since March 1998, Defendants have sought to increase Plavix sales and market share by making false and misleading superiority claims about Plavix relative to aspirin, the traditional treatment for patients with or at risk for atherosclerosis. Aspirin costs approximately $.04 per pill, while Plavix costs approximately $4.00 per pill.

49. The efficacy and safety of Plavix and aspirin for treatment of patients at risk for ischemic events were studied in the *Clopidogrel vs. Aspirin in Patients at Risk for Ischemic Events* ("CAPRIE") clinical trial, the results of which were published in 1996. The CAPRIE trial studied 19,185 patients who were divided into three subgroups of approximately 6,300 patients. The three subgroups were respectively comprised of: (1) patients who

experienced a recent stroke; (2) patients who experienced recent myocardial infarction; and (3) patients who experienced symptomatic PAD. Half of the patients in each subgroup were given 325 mg of aspirin once daily and the other half were given 75 mg of Plavix once daily. The primary objective of the study was to compare the rates of ischemic stroke, myocardial infarction, and vascular death between patients taking Plavix and patients taking aspirin.

50. The CAPRIE trial results showed an absolute risk reduction of only 0.5%. In other words, out of every 1,000 patients, a mere 5 patients experienced a benefit from treatment with Plavix in comparison to treatment with aspirin. While Plavix showed a slightly significant relative risk reduction of 8.7%, that figure was based in large part on the results in the PAD subgroup, which demonstrated a relative risk reduction of 23.8%. In the subgroups comprised of patients who had a recent stroke or myocardial infarction, the trial results did not show that Plavix had a statistically significant risk reduction; in fact, aspirin had a greater relative risk reduction than Plavix in patients who had a recent myocardial infarction. Plaintiff is informed and believes, and based thereupon alleges, that notwithstanding those results, since Plavix's product launch in March 1998, Defendants have falsely and misleadingly marketed Plavix as being superior to aspirin in treating stroke and heart attack patients in order to take market share away from aspirin medications.

51. Plaintiff is also informed and believes, and based thereupon alleges, that since March 1998, Defendants have falsely and misleadingly promoted Plavix and the CAPRIE trial results by not fully disclosing the results of the trial's subgroups, and by minimizing and failing to provide all of the data concerning adverse events occurring in the CAPRIE trial and other clinical trials involving Plavix.

52. Relatedly, Plaintiff is informed and believes, and based thereupon alleges, that since March 1998, Defendants have falsely and misleadingly promoted Plavix for primary prevention of disease, including primary prevention of strokes and myocardial infarctions, in all patients at risk for atherosclerosis. Plavix has not been approved for primary prevention, and it is not the standard of care. Generic aspirin remains the standard of care for patients with or at risk for atherosclerosis.

53. Similarly, Plaintiff is informed and believes, and based thereupon alleges, that since March 1998, Defendants have also falsely and misleadingly promoted Plavix as being more effective and safer than other competitors, such as Aggrenox, in order to increase Plavix's sales and market share. On information and belief, Defendants' strategy with respect to such competitors was similar to its strategy regarding aspirin in that Defendants made false and misleading statements about clinical trials involving those competitors when the trial results did not support Defendants' marketing messages.

54. Plaintiff is also informed and believes, and based thereupon alleges, that Defendants falsely and misleadingly promoted Plavix at much higher dosages than those approved by the FDA in order to compensate for the drug's low efficacy, while failing to disclose that Plavix is associated with hemorrhagic adverse events at its recommended dosage and that higher dosages of Plavix increase the risk of those and other adverse events associated with Plavix.

55. Further, Plaintiff is informed and believes, and based thereupon alleges, that since March 1998, Defendants have also increased Plavix's sales and market share by falsely and misleadingly promoting the drug as being effective and safe for uses for which it had not been demonstrated to be effective or safe.

56. In 2010, the ASA confirmed what Defendants knew or should have known all along when the ASA amended its *Guidelines for the Prevention of Stroke in Patients with Ischemic Stroke or Transient Ischemic Attack* (the "2010 ASA *Guidelines*") and stated that "[n]o studies have compared clopidogrel with placebo, and studies comparing it with antiplatelet agents have not clearly established that it is superior or equivalent to any one of them."

57. The 2010 ASA *Guidelines* also stated that "there have been no clinical trials to indicate that switching antiplatelet agents reduces the risk for subsequent events." Plaintiff is informed and believes, and based thereupon alleges, that Defendants knew or should have known that switching patients from another antiplatelet medication to Plavix had not been shown to reduce the risk for subsequent events, yet Defendants have falsely, deceptively, and unfairly misrepresented and promoted such medication changes at all relevant times in order to increase Plavix's sales and market share.

58. In addition, Plaintiff is informed and believes, and based thereupon alleges, that Defendants have falsely, deceptively, and unfairly marketed Plavix by failing to timely disclose the results of the *Clopidogrel for High Atherothrombotic Risk and Ischemic Stabilization, Management, and Avoidance* ("CHARISMA") trial that showed no benefit of combination therapy in patients taking Plavix and aspirin versus patients taking aspirin alone. The CHARISMA trial also showed a significant increase in bleeding symptoms in patients taking Plavix and aspirin versus patients taking aspirin alone.

59. Defendants' marketing efforts also encompassed their labeling of Plavix, as indicated above. At all relevant times, Defendants made false or misleading statements and representations about Plavix's efficacy in the drug's labeling, including its package insert or label, as well as in

sales materials, and other promotional materials and efforts.

60. Upon information and belief, at all relevant times, Defendants made the foregoing statements and omissions about Plavix's purported efficacy and superiority to healthcare providers and the general public throughout the nation, including New Mexico.

C. Additional False, Deceptive, and Unfair Conduct Concerning Important Safety Information

61. With respect to safety, the CAPRIE trial results showed less gastrointestinal bleeding in patients taking Plavix than in patients taking aspirin. But, the dosage of aspirin used in the trial—325 mg daily—is more than four times higher than the average dosage physicians advise for their patients. Physicians' average recommended dosage of 81 mg daily is just as effective as the 325 mg daily dosage but much less likely to lead to gastrointestinal bleeding. Plaintiff is informed and believes, and based thereupon alleges, that Defendants knew or should have known of the misleading nature of the CAPRIE trial results since at least March 1998, yet Defendants falsely and misleadingly marketed Plavix as being as safe or safer than aspirin based on the CAPRIE trial results. Plaintiff is also informed and believes, and based thereupon alleges, that since March 1998, Defendants have misrepresented and failed to adequately disclose important safety information about Plavix revealed in the CAPRIE trial, other clinical trials, and other sources of adverse event information, including information showing that Plavix is less safe than aspirin.

62. Although Defendants have never compared Plavix to a lower dosage of aspirin in a clinical trial, in *Clopidogrel versus Aspirin and Esomepraxole to Prevent Recurrent Ulcer Bleeding*, a study published in the New England Journal of Medicine in January 2005, Plavix was

demonstrated to cause appreciably more gastrointestinal bleeding than aspirin taken in conjunction with Prilosec, an inexpensive over-the-counter drug, in patients with a history of aspirin-induced ulcers. The study demonstrated that switching patients who had aspirin-induced ulcers from aspirin to Plavix is neither safe nor anywhere near as cost-effective as adding Prilosec to aspirin therapy. Plaintiff is informed and believes, and based thereupon alleges, that Defendants were aware of that circumstance many years before that study was published, and did not disclose the results of that study to healthcare professionals or the general public after the study was published, but rather continued to falsely and misleadingly market Plavix as being as safe or safer than aspirin.

63. Plaintiff is informed and believes, and based thereupon alleges, that since March 1998, Defendants have falsely and misleadingly marketed Plavix as having a lower risk of gastrointestinal bleeding than aspirin in patients with an increased risk of gastrointestinal bleeding.

64. Plaintiff is informed and believes, and based thereupon alleges, that since at least March 1998, Defendants knew or should have known that Plavix causes more gastrointestinal bleeding and other complications than other antiplatelet medications, yet Defendants misrepresented and failed to adequately disclose that information to healthcare providers and the general public.

65. Plaintiff is informed and believes, and based thereupon alleges, that since March 1998, Defendants have misrepresented and failed to adequately disclose that patients are at a higher risk of gastrointestinal bleeding and other complications when taking aspirin in conjunction with Plavix than when taking aspirin alone.

66. Plaintiff is informed and believes, and based thereupon alleges, that since at least August 2001, Defendants have misrepresented and failed to adequately

disclose that elderly patients taking Plavix have an increased risk of gastrointestinal bleeding as compared to younger patients taking Plavix.

67. As noted above, Defendants' marketing efforts also encompassed their labeling of Plavix. At all relevant times, Defendants made false or misleading statements and representations about Plavix's safety in the drug's labeling, including its package insert or label, sales materials, and other promotional materials and efforts.

68. Upon information and belief, at all relevant times, Defendants made the foregoing statements and omissions about Plavix's safety to healthcare providers and the general public throughout the nation, including New Mexico.

D. Defendants' False and Misleading Representations and Omissions Regarding the Alleged Effectiveness, Safety and Superiority of Plavix Caused Third Parties to Submit Claims for Reimbursement to the State of New Mexico That Were False Within the Meaning of New Mexico Law

69. Defendants, in marketing Plavix, knew that pharmacies and other facilities supplying Plavix to patients throughout New Mexico would routinely be seeking reimbursement from the State of New Mexico under its Medicaid (and related) programs. As a result, Defendants, by promoting Plavix as safer and more effective than other medications when it was not, at 100 times the cost of available alternatives, knowingly caused innocent third parties to submit claims for reimbursement to the State of New Mexico that Defendants knew or should have known did not qualify for payment.

70. By doing so, Defendants obtained, by means of false or fraudulent representation or promise, large sums of money from the State of New Mexico in connection with delivery of or payment for health care benefits that are in

whole or in part paid for or reimbursed or subsidized by the state.

71. Defendants benefited from this deception by increased prescriptions of Plavix, resulting in increased profits for Defendants.

72. In addition, Defendants' misleading conduct, statements and omissions regarding the alleged effectiveness, superiority, and safety of Plavix deprived physicians and the State of New Mexico of the ability to accurately determine whether the drug was in fact "medically necessary" in any given situation.

73. By writing prescriptions for Plavix for which reimbursement would be sought through public assistance programs, physicians were certifying by implication that the treatment was safe, medically necessary and cost-effective, when in fact it was not, because Plavix was ineffective or unsafe or both.

74. Therefore, by causing physicians to unwittingly certify that Plavix was medically necessary and cost-effective when it was not, Defendants knowingly caused the submission of a false claims to the State of New Mexico in violation of New Mexico law.

E. The FDA's Repeated Objections to Defendants' False, Deceptive, and Unfair Marketing

75. As discussed more fully above, Defendants have systematically and deliberately promoted Plavix through false and misleading marketing that overstates the drug's efficacy, advances unsubstantiated superiority claims, and minimizes critical adverse event and risk information. As a result, the FDA has repeatedly admonished Defendants' promotion of Plavix.

76. For example, on November 23, 1998, the FDA's Division of Drug Marketing, Advertising, and Communications ("DDMAC") reprimanded Sanofi, stating that Defendants' dissemination of a letter, purportedly authored

by a physician, violated the Federal Food, Drug, and Cosmetic Act ("FDCA") because it promoted Plavix for an unapproved use (immediately prior to coronary artery stent placement) and an unapproved dose (300 mg loading dose), as well as because it lacked fair balance in failing to disclose safety risks associated with the use of Plavix. In particular, the letter explained as follows: "Because Plavix is associated with hemorrhagic adverse events at recommended 75 mg/day dose, promotion of Plavix in patients receiving coronary artery intervention, at four times the recommended dose, in combination with other agents known to increase the risk of bleeding, raises significant patient safety concerns."

77. On December 18, 1998, DDMAC again admonished Sanofi, stating that multiple promotion materials it disseminated—a brochure, a journal advertisement, and a video—contained promotional claims that were false or misleading and lacking in fair balance because they made unsubstantiated superiority claims about Plavix relative to aspirin, overstated Plavix's efficacy, and minimized or failed to adequately present adverse event and risk information.

78. On May 9, 2001, DDMAC alerted Sanofi that its dissemination of a particular visual aid for Plavix contained false or misleading promotional claims because it overstated the drug's efficacy, included an unsubstantiated superiority claim about Plavix relative to aspirin, and included a misleading efficacy presentation. In particular, the Warning Letter stated:

> On page 4 of the visual aid you present the claim, "Significant overall risk reduction vs. aspirin 325 mg in CAPRIE, a 3 year study of 19,185 patients." This claim is misleading because it suggests that Plavix is superior to aspirin when such has not been demonstrated by substantial evidence. ***As previously stated in our December 18, 1998, untitled letter, the CAPRIE trial does not provide substantial***

> ***evidence to support the implication that Plavix has superior efficacy over aspirin. Therefore, claims suggesting that Plavix is significantly better than aspirin are misleading*** because they are not based on substantial evidence.

79. On June 9, 2001, DDMAC again reprimanded Sanofi, stating that the dissemination of a direct-to-consumer television advertisement for Plavix was misleading and violated regulatory requirements because it minimized the role of physicians in determining whether Plavix is the appropriate therapy for a patient's condition, and because it did not ensure adequate provision for disseminating Plavix's approved product labeling.

80. On March 26, 2009, DDMAC again reprimanded Sanofi, stating that three of its internet advertisements were misleading because they made representations or suggestions about the efficacy of Plavix but failed to communicate any risk information associated with the use of the drug, thereby indicating that Plavix is safer than has been demonstrated.

F. The Impact of Defendants' False, Deceptive, and Unfair Marketing of Plavix

81. As discussed above, Defendants launched and maintained a massive promotional campaign to increase Plavix's sales and market share. Plavix's blockbuster sales were driven by Defendants' decision to put marketing, sales, and corporate profits ahead of science and patient safety. Plaintiff is informed and believes, and based thereupon alleges, that Defendants knew that the dissemination of information about Plavix's true efficacy and safety profile would devastate Plavix's sales and make Plavix unable to compete with other established, cheaper, and safer atherosclerosis therapies. Thus, Defendants chose, and continue to choose, to put their corporate profits ahead of patients' safety and repeatedly failed, and

continued to fail, to disclose critical efficacy and safety information about Plavix, including information about diminished or no responsiveness to Plavix that has led to the need for a black box warning on Plavix's label.

82. As shown above, Defendants' corporate strategy and business model is dictated not by science, but by sales and marketing. Plaintiff is informed and believes, and based thereupon alleges, that Defendants' marketing and commercial personnel exert extensive control over scientific and medical decisions, such as the initiation of clinical trials, the types of trials done, the design of those trials, and the reporting and publication of trial data, all with the ultimate goal of producing further support for Defendants' marketing messages and bolstering sales of Plavix.

83. On information and belief, Defendants also obscured or failed to report important safety information, including information relating to Plavix's risk of gastrointestinal bleeding, because doing so would jeopardize Plavix's sales and would be inconsistent with Defendants' key marketing and sales messages, as discussed above. Defendants' top priority is neither science nor safety, but rather marketing. Marketing concerns infected and distorted Defendants' entire Plavix scientific program and continue to do so to this today.

84. Further, Plaintiff is informed and believes, and based thereupon alleges, that Defendants maintained a marketing-based publication strategy designed to misleadingly influence medical and scientific literature by promoting the publication of medical and scientific articles that would support their marketing messages about Plavix's efficacy and safety and/or suggest dissatisfaction with competing therapies. On information and belief, that strategy included practices such as ghostwriting articles and hiring outside ghostwriting companies, giving Defendants' marketing personnel editorial and substantive input into decisions about what scientific studies to

publish and the actual content of such publications, and forming misleading financial and promotional relationships with authors, "opinion leaders," and other physicians. On information and belief, Defendants gave their marketing departments extensive control over Defendants' research and publication decisions so that medical and scientific publications could be used as tools to promote Defendants' Plavix marketing messages.

85. In short, Defendants have profited tremendously by making false and misleading statements and representations regarding Plavix's efficacy and safety, as detailed above.

86. Plaintiff is informed and believes, and based thereupon alleges, that Defendants' conduct described herein is only a fraction of their false and misleading Plavix marketing.

87. Defendants failed to adequately disclose facts sufficient to arouse suspicion of the existence of the claims that Plaintiff now asserts. Plaintiff was not alerted to the existence and scope of Defendants' wrongful conduct and the claims arising from such conduct, and could not have acquired such knowledge earlier through the exercise of reasonable diligence. Through their public statements, marketing, and advertising, Defendants' self-concealing scheme and affirmative conduct to perpetuate that scheme deprived New Mexico patients, their insurers, public healthcare providers, public entities, and government payors of actual or presumptive knowledge of facts sufficient to put them on notice of potential claims.

88. Defendants' far-reaching, massive, and widespread promotional campaign to drive Plavix's sales was specifically directed at and did influence the State of New Mexico. Defendants' sales representatives, lobbyists, Defendants' "opinion leaders", and company "scientists" presented false and misleading information regarding the

safety and efficacy of Plavix which was reasonably relied upon by the State of New Mexico.

89. In addition, Defendants, through their control and manipulation of studies and research publications, their sponsorship of medical education programs, their submission of false and misleading information to the FDA, their use of "opinion leaders", their failure to adequately warn of Plavix's true risks in their labeling and other marketing materials, and their false and deceptive marketing conducted by Defendants' sales representatives, lobbyists, "opinion leaders", and company "scientists", caused false and misleading information regarding the safety and efficacy of Plavix to be reasonably relied upon by the State of New Mexico.

90. Defendants engaged in a premeditated program to influence consumers, prescribers, and the State of New Mexico to believe that Plavix was a superior drug when it was not.

91. The financial toll that Defendants' false and deceptive marketing of Plavix has had on the State of New Mexico has been dramatic. Relying upon Defendants; promises of superior treatment and better outcomes compared with aspirin and other competitor drugs, the State of New Mexico paid a hefty premium for a drug that in truth was no more efficacious than far cheaper drugs, but was far more dangerous.

92. The State of New Mexico seeks the most effective and safest treatment for its residents and relies on pharmaceutical companies to fairly and accurately represent the safety and efficacy of their products. Defendants have wholly violated that trust, and instead have perpetrated their fraudulent scheme to defraud the State of New Mexico, and have bilked the State of New Mexico out of millions of dollars by making false representations that Plavix was better than existing medications, and could decrease ischemic risks.

93. Defendants' false, misleading, and deceptive marketing of Plavix resulted in millions of dollars of Plavix sales to the State of New Mexico, sales that otherwise would not have been made. Defendants were unjustly enriched and profited from the suppression of the truth and misleading promotion of Plavix.

94. Defendants' false, misleading and deceptive marketing of Plavix also resulted in State of New Mexico participants who took Plavix experiencing gastrointestinal bleeding. As a result, the State of New Mexico has borne and will bear additional costs for the care and treatment of these undisclosed increased incidents of bleeding.

95. This Complaint is based solely upon the laws of the State of New Mexico, and contains causes of action found within those laws. To the extent that the Defendant asserts that any claim contained herein raises a substantial question of federal law or a federal cause of action, Plaintiff hereby disavows any such claim.

II. STATUTES OF LIMITATIONS HAVE NOT RUN AGAINST THE STATE ON ANY CAUSE OF ACTION IT HAS ALLEGED

96. The general rule is that statutes of limitations do not run against the State unless the statute expressly includes the State or does so by clear implications. *See Bd. Of Ed., Sch. Dist. 16, Artesia, Eddy Cty v. Standhardt*, 1969-NMSC-118, ¶ 17, 80 N.M. 543. Since no statute implicated by any cause of action the State has asserted expressly includes the State or does so by clear implication, the State's claims are not barred by any statute of limitation.

COUNT I

VIOLATIONS OF THE NEW MEXICO UNFAIR PRACTICES ACT
[NMSA 1978, Section 57-12-3]

97. The State repeats and reiterates the allegations previously set forth herein.

98. Defendants' acts and omissions complained of in paragraphs 27-80, constitute false or misleading oral or written statements or other representations and omissions that Defendants knowingly made in the regular course of their trade and in connection with the sale of their goods, which may have, tended to, or did deceive or mislead consumers and medical professionals. These acts and omissions constitute unfair and deceptive trade practices as defined under Section 57-12-2(D) and in violation of Section 57-12-3.

99. Defendants engaged in the above-described acts and omissions intentionally and with knowledge that harm might result, and thus willfully as defined under Section 57-12-11.

100. Defendants engaged in unfair or deceptive acts or practices by failing to disclose, in Plavix's labeling and otherwise, that Plavix has diminished or no effect on a significant percentage of the patient population.

101. Defendants also engaged in unfair or deceptive acts or practices by making statements about Plavix's efficacy and/or safety, in Plavix's labeling and otherwise, without disclosing that Plavix has diminished or no effect on a significant percentage of the patient population.

102. Defendants also engaged in unfair or deceptive acts or practices by falsely and misleadingly marketing Plavix as being more effective and safer than aspirin in Plavix's labeling and otherwise.

103. Defendants also engaged in unfair or deceptive acts or practices by failing to disclose, in Plavix's labeling and otherwise, that Plavix has a greater chance of causing gastrointestinal bleeding and other complications than aspirin.

104. Defendants' willful and repeated acts and omissions relating to Plavix, as described above constitute unfair or deceptive acts or practices in the conduct of commerce, both of which violate the New Mexico Unfair Practices Act, NMSA 1978, Section 57-12-3, including:

a. Defendants represented that Plavix has characteristics, uses and benefits that it does not have, in violation of NMSA 1978, Section 57-12-2 (D)(5).

b. Defendants represented that Plavix has superior benefits as compared to other competitor medications that it does not have, in violation of NMSA 1978, Section 57-12-2 (D)(7).

c. Defendants represented that Plavix was a safe and effective drug when such representations were untrue, false and misleading, in violation of NMSA 1978, Section 57-12-2 (D)(7).

d. Defendants engaged in conduct using exaggeration, innuendo or ambiguity as to material facts regarding the risk-benefit profile of Plavix which created a likelihood of confusion and misunderstanding, in violation of NMSA 1978, Section 57-12-2 (D)(14).

e. Defendants made deceptive representations of material facts regarding Plavix, in violation of NMSA 1978, Section 57-12-2 (D)(14).

f. Defendants' promotional activities regarding Plavix, including publishing and distributing statements which were misleading and deceptive, and which omitted material information necessary to make the statements not be misleading and deceptive, or tending to deceive, were in violation of NMSA 1978, Section 57-12-2 (D)(14).

g. Defendants' conduct constitutes an unconscionable trade practice in that it took advantage of the lack of knowledge of the State, New Mexico health care professionals and State of New Mexico participants regarding Plavix's risk-benefit profile, in violation of NMSA 1978, Section 57-12-2 (E)(1).

h. Defendants' conduct constitutes an unconscionable trade practice in that it resulted in a gross disparity between the value received and the price paid, in violation of NMSA 1978, Section 57-12-2 (E)(2).

105. Each exposure of a state employee or contractor, New Mexico health care professional or New Mexico patient to misleading and deceptive information regarding Plavix communicated in any manner by a sales representative constitutes a separate violation pursuant to NMSA 1978, Section 57-12-11.

106. Each exposure of a state employee or contractor, New Mexico health care professional or New Mexico patient to a misleading and/or deceptive print advertisement regarding Plavix constitutes a separate violation pursuant to NMSA 1978, Section 57-12-11.

107. Each exposure of a state employee or contractor, New Mexico health care professional or New Mexico patient to a misleading and/or deceptive brochure regarding Plavix constitutes a separate violation pursuant to NMSA 1978, Section 57-12-11.

108. Each exposure of a state employee or contractor, New Mexico health care professional or New Mexico patient to other misleading and/or deceptive information regarding Plavix, provided directly or indirectly by Defendants, e.g., by means of package labeling, warning, Dear Healthcare Provider letters, CD-ROMs, DVDs, dinners sponsored by Defendants, PowerPoint presentations, promotional items, continuing medical education materials and events sponsored by Defendants and

meetings sponsored by Defendants, constitutes a separate violation pursuant to NMSA 1978, Section 57-12-11.

109. Each piece of marketing material used or disseminated in New Mexico which contained false or deceptive representations constitutes a separate, distinct, knowing and willful violation of the Unfair Practices Act.

110. Each Plavix prescription written in New Mexico without an adequate warning constitutes a separate and distinct violation of the Unfair Practices Act.

111. Each exposure of a New Mexico resident to Plavix resulting from the aforementioned conduct of Defendants constitutes a separate violation pursuant to NMSA 1978, Section 57-12-11.

112. To the extent applicable, Defendants cannot invoke the "Safe Harbor" provisions of the Unfair Practices Act because of their complete failure to disclose at least the following known risks to the FDA in a timely manner:

a. the genetic variations of the CYP2C19 enzyme that cause Plavix to metabolize poorly in a significant percentage of the patient population;

b. the prevalence of those genetic variations in certain populations (e.g., Caucasian, African, and Asian);

c. that a defect in the CYP2C19 enzyme interfered with the metabolization of numerous drugs, including Plavix;

d. that the defect in the CYP2C19 enzyme that interfered with the metabolization of numerous drugs, including Plavix, could be tested through a simple genetic test;

e. that Plavix has diminished or no effect on patients who are CYP2C19 poor metabolizers;

f. that Plavix was not more effective and safer than aspirin;

g. the factors that gave rise to the misleading nature of the CAPRIE trial results;

h. that Plavix is less effective in elderly patients than in younger patients;

i. that elderly patients taking Plavix have an increased risk of gastrointestinal bleeding compared to younger patients taking Plavix;

j. that Plavix is not more effective and safer than competitor drugs;

k. that Plavix was demonstrated to cause appreciably more gastrointestinal bleeding than aspirin taken in conjunction with Prilosec;

l. that switching patients who had aspirin-induced ulcers from aspirin to Plavix is neither safe nor anywhere near as cost-effective as adding Prilosec to aspirin therapy; and

m. that patients are at a higher risk of gastrointestinal bleeding and other complications when taking aspirin in conjunction with Plavix than when taking aspirin alone.

113. Defendants' violations of the Unfair Practices Act were and continue to be willful.

114. Unless enjoined from doing so, Defendants will continue to violate the New Mexico Unfair Practices Act.

115. The State seeks reimbursement of all monies paid for Plavix by the State of New Mexico.

116. The State of New Mexico also seeks restitution for all monies paid for Plavix in connection with State of New Mexico programs and/or by state agencies and/or departments.

117. The State of New Mexico also seeks disgorgement of profits from Defendants for all sales of Plavix in connection with State of New Mexico programs and/or by state agencies and/or departments.

118. The State of New Mexico also seeks all recoverable penalties under Section 57-12- 11 for violations of the New Mexico Unfair Practices Act.

COUNT II

VIOLATIONS OF THE NEW MEXICO FRAUD AGAINST TAXPAYERS ACT [NMSA 1978, Section 44-9-3]

119. The State repeats and reiterates the allegations previously set forth herein.

120. Defendants' willful and repeated acts and omissions relating to Plavix, as described above, violate the New Mexico Fraud Against Taxpayers Act, NMSA 1978, Section 44-9-3.

121. In representing that Plavix had superior efficacy than other established drugs, by failing to disclose that Plavix has diminished or no effect on a significant percentage of the patient population, by falsely and misleadingly marketing Plavix as being more effective and safer than aspirin, by failing to disclose, in Plavix's labeling and otherwise, that Plavix has a greater chance of causing gastrointestinal bleeding and other complications than aspirin, by falsely and misleadingly marketing Plavix as more effective and safer than other competitor drugs, by falsely and misleadingly marketing Plavix as effective and safe for uses for which the drug had not been shown to be effective, by falsely and misleadingly marketing Plavix as having a lower risk of gastrointestinal bleeding than aspirin in patients with an increased risk of gastrointestinal bleeding, by falsely and misleadingly marketing Plavix as being as safe and effective in elderly patients as in younger patients and in failing to disclose the true facts regarding safety and efficacy of Plavix, Defendants knowingly presented, or caused to be presented, false claims

for payment or approval, in violation of NMSA 1978, Section 44-9-3A(1).

122. In representing that Plavix had superior efficacy than other established drugs, by failing to disclose that Plavix has diminished or no effect on a significant percentage of the patient population, by falsely and misleadingly marketing Plavix as being more effective and safer than aspirin, by failing to disclose, in Plavix's labeling and otherwise, that Plavix has a greater chance of causing gastrointestinal bleeding and other complications than aspirin, by falsely and misleadingly marketing Plavix as more effective and safer than other competitor drugs, by falsely and misleadingly marketing Plavix as effective and safe for uses for which the drug had not been shown to be effective, by falsely and misleadingly marketing Plavix as having a lower risk of gastrointestinal bleeding than aspirin in patients with an increased risk of gastrointestinal bleeding, by falsely and misleadingly marketing Plavix as being as safe and effective in elderly patients as in younger patients and in failing to disclose the true facts regarding safety and efficacy of Plavix, Defendants knowingly made, used, or caused to be made or used, false, misleading or fraudulent statements to obtain or support the approval of, or the payment on, false or fraudulent claims, in violation of NMSA 1978, Section 44-9-3A(2).

123. By engaging in the wrongful conduct described herein, Defendants conspired to defraud the State by obtaining approval or payment on false or fraudulent claims.

124. On information and belief, Defendants' clinical research and publication strategies were directed and influenced largely by marketing concerns rather than by medical or safety concerns, and Defendants' management allowed marketing personnel to direct the company's so-called scientific research rather than enabling independent analysis. Defendants repeatedly failed to disclose important safety information; they improperly and

deceptively influenced the medical and scientific literature and the perception of Plavix within the medical community; they consistently downplayed Plavix's risks; they formed deceptive and misleading financial and promotional relationships with "opinion leaders," speakers and other physicians for the purpose of promoting the product; they engaged in misleading sales training, sales tactics, and marketing to prescribers, participants in State programs, and/or the State of New Mexico that misrepresented the safety and efficacy of Plavix; they engaged in the ghostwriting of medical and scientific articles; and they engaged in other deceptive and misleading marketing, lobbying, public relations, and sales practices as described herein. Defendants marketed Plavix as safe and effective with the intent that the State rely on their representations so that the medical providers would not prescribe, and the State pay for, other effective, safe competitor drugs.

125. In addition, Defendants, through their control and manipulation of studies and research publications, their sponsorship of medical education programs, their submission of false and misleading information to the FDA, their use of "opinion leaders", their failure to adequately warn of Plavix's true risks in their labeling and other marketing materials, and their false and deceptive marketing conducted by their sales representatives, lobbyists, and "opinion leaders," caused false and misleading information regarding the safety and efficacy of Plavix to be reasonably relied upon by the State of New Mexico.

126. Defendants' aggressive, illegal promotions have induced a misallocation of State funds through a pattern of fraudulent conduct. Defendants made or caused false claims, statements and representations of material fact to be made in connection with the State of New Mexico programs and/or in connection with expenditures made by State agencies and/or departments. In addition,

Defendants knowingly and willfully concealed or failed to disclose material facts, events and/or transactions which affected Defendants' entitlement to payment, reimbursement, or benefits under the State's programs or by State agencies and/or departments, and/or the amount of payment, reimbursement, or benefit to which the Defendants were entitled for services, goods or assistance rendered in connection with the State's programs and/or to State agencies and/or departments. Defendants' scheme included the implementation of intentionally deceptive marketing practices. Defendants intended that their fraudulent promotions be relied upon for the expenditure of public money, and result in the reimbursement of prescriptions by the State of New Mexico.

127. As a result of Defendants' fraudulent marketing of Plavix, the State of New Mexico has paid millions of dollars for Plavix and has paid excessive prices for Plavix. As a result, Defendant has been illegally enriched at the expense of the State of New Mexico. Further, the State of New Mexico has been required and will be required to pay the costs of treatment of State of New Mexico participants actively harmed by Defendants' actions.

128. In representing that Plavix had superior efficacy than other established drugs, by failing to disclose that Plavix has diminished or no effect on a significant percentage of the patient population, by falsely and misleadingly marketing Plavix as being more effective and safer than aspirin, by failing to disclose, in Plavix's labeling and otherwise, that Plavix has a greater chance of causing gastrointestinal bleeding and other complications than aspirin, by falsely and misleadingly marketing Plavix as more effective and safer than other competitor drugs, by falsely and misleadingly marketing Plavix as effective and safe for uses for which the drug had not been shown to be effective, by falsely and misleadingly marketing Plavix as having a lower risk of gastrointestinal bleeding

than aspirin in patients with an increased risk of gastrointestinal bleeding, by falsely and misleadingly marketing Plavix as being as safe and effective in elderly patients as in younger patients and in failing to disclose the true facts regarding safety and efficacy of Plavix, Defendants acted with actual knowledge of the falsity of the representations or acted in either deliberate ignorance or reckless disregard of the truth or falsity of the information. Defendants' wrongful conduct resulted in charges to the State of New Mexico for goods or services that were so deficient as to be worthless.

129. Each claim for Plavix presented to the State of New Mexico or to a contractor, grantee or other recipient of state funds constitutes a separate violation pursuant to NMSA 1978, Section 44-9-3.

130. In addition to, or in the alternative, each exposure of a state employee or contractor, New Mexico health care professional or State of New Mexico participant to misleading and deceptive information regarding Plavix communicated in any manner by a sales representative made or used, or caused to be made or used to obtain or support the approval of or the payment on a claim for Plavix constitutes a separate violation pursuant to NMSA 1978, Section 44-9-3.

131. In addition to, or in the alternative, each exposure of a state employee or contractor, New Mexico health care professional or State of New Mexico participant to a misleading and/or deceptive print advertisement regarding Plavix made or used, or caused to be made or used to obtain or support the approval of or the payment on a claim for Plavix constitutes a separate violation pursuant to NMSA 1978, Section 44-9-3.

132. In addition to, or in the alternative, each exposure of a state employee or contractor, New Mexico health care professional or State of New Mexico participant to a misleading and/or deceptive brochure regarding Plavix

made or used, or caused to be made or used to obtain or support the approval of or the payment on a claim for Plavix constitutes a separate violation pursuant to NMSA 1978, Section 44-9-3.

133. In addition to, or in the alternative, each exposure of a state employee or contractor, New Mexico health care professional or State of New Mexico participant to other misleading and/or deceptive information regarding Plavix made or used, or caused to be made or used to obtain or support the approval of or the payment on a claim for Plavix constitutes a separate violation pursuant to NMSA 1978, Section 44-9-3.

134. In addition to, or in the alternative, each piece of marketing material used or disseminated in New Mexico which contained false or deceptive representations regarding Plavix made or used, or caused to be made or used to obtain or support the approval of or the payment on a claim for Plavix constitutes a separate violation pursuant to NMSA 1978, Section 44-9-3.

135. In addition to, or in the alternative, each Plavix prescription written in New Mexico in connection with State of New Mexico programs without an adequate warning constitutes a separate and distinct violation of the New Mexico Fraud Against Taxpayer's Act.

136. As a direct and proximate result of Defendants' wrongful conduct, the State of New Mexico and it citizens have suffered and will continue to suffer substantial damage and injury as a result of Defendants' violations of the New Mexico Fraud Against Taxpayer's Act.

137. Pursuant to the New Mexico Fraud Against Taxpayer's Act, the State is entitled to three times the amount of damages sustained by the State because of Defendants' violations of the New Mexico Fraud Against Taxpayer's Act, a civil penalty of not less than five thousand dollars ($5,000) and not more than ten thousand

dollars ($10,000) for each violation, reasonable attorneys' fees, and costs.

COUNT III

FRAUD

138. Plaintiff repeats and reiterates the allegations previously set forth herein.

139. Defendants' warnings of Plavix contained false representations and/or failed to accurately represent the material facts of the full range and severity of risks and adverse reactions associated with the product.

140. Defendants' Plavix-related representations and assertions to the State of New Mexico, prescribers, and State of New Mexico participants contained intentional misrepresentations and material omissions as to the safety of Plavix and its defective design.

141. Defendants were negligent in not making accurate representations regarding the side effects and adverse medical conditions associated with the use of Plavix.

142. Defendants knew or reasonably should have known through adequate testing that the representations made to the State with regard to the safety and efficacy of Plavix were false or incomplete, and misrepresented the material facts of Plavix's unsafe and defective condition.

143. The State, through its programs, departments and agencies, expended millions of dollars for Plavix prescriptions which were directly caused by the fraudulent and misleading statements of the Defendants.

144. Defendants willfully, knowingly and deceptively withheld material facts regarding the risks and side effects associated with Plavix from the State of New Mexico, prescribers, and State of New Mexico participants.

145. Defendants intentionally withheld information regarding the safety risks and side effects associated with

Plavix with the intent to induce the State of New Mexico, prescribers and State of New Mexico participants.

146. The State of New Mexico, prescribers and State of New Mexico participants were justified in their reliance on Defendants to educate them as to the risks and dangerous and potentially life-threatening side effects associated with Plavix use.

147. Defendants' far-reaching, massive, and widespread promotional campaign to drive Plavix's sales was specifically directed at and did influence the State of New Mexico. Defendants' sales representatives, lobbyists, "opinion leaders", and company "scientists" directly communicated with the State of New Mexico, and in connection therewith, presented false and misleading information regarding the safety and efficacy of Plavix which was reasonably relied upon by the State of New Mexico.

148. In addition, Defendants, through their control and manipulation of studies and research publications, their submission of false and misleading information to the FDA, their use of "opinion leaders", their failure to adequately warn of Plavix's true risks in their labeling and other marketing materials, and their false and deceptive marketing conducted by Defendant sales representatives, lobbyists and "opinion leaders," caused false and misleading information regarding the safety and efficacy of Plavix to be reasonably relied upon by the State of New Mexico.

149. Defendants' aggressive, illegal promotions have induced a misallocation of State funds through a pattern of fraudulent conduct which caused false claims to be submitted to the State of New Mexico's programs, agencies and departments. Defendants executed and conspired to execute a plan to defraud the State of New Mexico in connection with the delivery of or payment for Plavix. Defendants' plan included the implementation of intentionally deceptive marketing schemes. Defendants intended that their fraudulent promotions would result in

the reimbursement of prescriptions by the State of New Mexico's programs, agencies and departments.

150. Each of the Defendants' misleading and deceptive statements, representations and advertisements related to Plavix were material to the State's reimbursement of Plavix.

151. As a proximate and legal result of Defendants' fraudulent misrepresentations, the State of State of New Mexico has suffered and will continue to suffer damages, and is therefore entitled to recover for those damages.

152. The reprehensible nature of the Defendants' conduct further entitles the State to an award of punitive damages.

COUNT IV

UNJUST ENRICHMENT

153. Defendants knowingly, willfully and intentionally marketed and promoted Plavix in a false and deceptive manner as more particularly alleged in paragraphs 27-80 above.

154. Defendants knowingly, willfully and intentionally withheld information from the State, prescribers and State of New Mexico participants regarding the risks associated with Plavix use.

155. The State paid, reimbursed or otherwise conferred a benefit upon Defendants that directly resulted from the Defendants' fraudulent marketing practices.

156. Further, Defendants have been unjustly enriched in the form of profits as a result of their fraudulent marketing practices.

157. As a matter of equity, Defendants should be required to disgorge their unjustly obtained profits from purchases of Plavix.

RELIEF REQUESTED

WHEREFORE, Plaintiff, the State of New Mexico, prays for judgment against Defendants as follows:

A. Adjudge and decree that Defendants engaged in conduct in violation of the New Mexico Unfair Practices Act, §57-12-1, *et seq*.,

B. Adjudge and decree that Defendants engaged in conduct in violation of the New Mexico Fraud Against Taxpayers Act, §44-9-1, *et seq.*;

C. Grant permanent injunctive relief and award restitution against Defendants pursuant to §57-12-8(B) NMSA 1978;

D. Award the State its damages as set forth herein;

E. Award the state restitution as set forth herein;

F. Award the State disgorgement of all Defendant's profits obtained as a result of Plavix sales in New Mexico;

G. Award maximum civil penalties as provided by law;

H. Award the State punitive damages;

I. Award the State the costs of prosecuting this action, together with interest, including prejudgment interest, and reasonable attorneys' fees in connection with the prosecution of this case; and

J. Grant further relief as this Court may deem just and proper under the circumstances.

DATED: January 05, 2018

Respectfully submitted,

OFFICE OF THE NEW MEXICO
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* * * * *

APPENDIX G

FIRST JUDICIAL DISTRICT COURT
COUNTY OF SANTA FE
STATE OF NEW MEXICO

STATE OF NEW MEXICO, ex rel
HECTOR BALDERAS, ATTORNEY GENERAL
Plaintiff,
vs.
BRISTOL-MEYERS SQUIBB COMPANY, et al,
Defendants.

D-101-CV-2016-2176

TRANSCRIPT OF PROCEEDINGS

On the 1st day of March 2017, this matter came on for hearing on MOTIONS before the HONORABLE SARAH SINGLETON, Judge of the First Judicial District, State of New Mexico.

The Plaintiff, STATE OF NEW MEXICO, appeared by Counsel of Record, CHOLLA KHOURY, MARCUS RAEL and DANIEL ALBERSTONE.

The Defendants, BRISTOL-MYERS SQUIBB COMPANY, et al, appeared by Counsel of Record, TIM HOLM, DREW HARKER.

At which time the following proceedings were held:

[2] March 1, 2017

(In open court.)

THE COURT: We are here today in the matter of State of New Mexico ex rel Hector Balderas Attorney

General, versus Bristol-Myers Squibb Company and others. It's D-101-CV-2016-02176. Will counsel for plaintiff enter appearances, please?

MR. ALBERSTONE: Good afternoon, Your Honor. Dan Alberstone appearing on behalf of the state.

MR. RAEL: Marcus Rael on behalf of the state.

MS. KHOURY: Cholla Khoury with the office of the New Mexico Attorney General's Office.

THE COURT: And for the defendants?

MR. HOLM: Your Honor, I'm Tim Holm for the defendants, and I would like to introduce you to my co-counsel, who is national counsel, Drew Harker from Arnold and Porter. Also at counsel table is Owen Dunn from Arnold and Porter. Owen is not pro hacced in, but he will be sitting at counsel table, if that's okay with the Court.

(CourtCall connection made.)

THE COURT: Would counsel who are appearing by telephone please state their names.

MR. AGNESHWAR: This Anand Agneshwar from Arnold and Porter.

MS. HENSON: Cecily Williams Henson with [3] Bristol-Myers Squibb Company.

MR. DOVDAVANY: Good afternoon, Dan Dovdavany from Santa Fe.

* * * * *

[7] * * *

MR. HARKER: So, as I said, Your Honor, the Dickson case was filed in 2011. New Mexico is a named party in the case. Just in 2016, a few short months ago, the state filed its own case here in New Mexico which is essentially

a copycat of the case pending in New Jersey, in particular, the Dickson case.

THE COURT: Well, it's not exactly a copycat.

MR. HARKER: Well, Your Honor, when you look at the claims that are pending in Dickson versus the claims that are filed here, you will see that in fact, of the 52 paragraphs -- of the 52 paragraphs that allege facts from the Dickson case, 47 of them are repeated in the New Mexico's case here in Santa Fe. So that's about 90 percent of the -- of the operative facts when you include both Dickson and JKJ. So there is a substantial overlap, Your Honor, of the claims in the two cases.

And I'm sure Your Honor is asking me that question because under the test in New Mexico, in addition to same parties, there is also -- also a test for same [8] claims. And here, I would submit to you, Your Honor, there are certainly enough of an overlap between the two cases to satisfy the same claims test.

In Dickson, the relator there alleges that defendants improperly marketed Plavix as superior to aspirin. That is a claim that is repeated by the attorney general here in New Mexico. In Dickson the relator claimed that the defendants improperly marketed Plavix as superior to drugs that it competed against. That is also repeated here in New Mexico, Your Honor.

In addition, in Dickson the relator claimed that the defendants improperly marketed Plavix as medically necessary, and that is also repeated here in New Mexico, Your Honor. In Dickson, the plaintiff, the relator claimed that the defendants misled doctors about the risk of bleeding with Plavix. That's also repeated in the New Mexico complaint.

The defendants also withheld information -- in Dickson, it was alleged earlier that defendants withheld information about so-called variability of response, meaning that individuals with a certain genetic trait may not be as responsive to Plavix as other people. That's also repeated in New Mexico.

The defendants in Dickson, the allegation is also that the defendants failed to disclose a certain subgroup [9] data from the Caprie clinical trial. That's also repeated in New Mexico. And that Dickson also alleged that the Caprie trial, which is the foundational study for Plavix, was conducted in a misleading way by using an inappropriate dosage of aspirin, and that's also repeated in New Mexico.

So we have this very, very substantial overlap, Your Honor, between the two cases, which I think clearly satisfies the same claims test. The test there is a so-called transactional test, and that looks for a common nucleus of operative facts and, I think, clearly, Your Honor, based on the overlap between the claims in Dickson, in JKJ, and the claims in the New Mexico case here, we -this -- this situation clearly satisfies the transactional test, you know, more on the common nucleus of operative facts, which was announced by Potter v. Pierce in New Mexico as the standard to apply.

So what Potter v. Pierce listed the factors to help determine if there is a common nucleus: Do the facts relate in time, space, origin and motivation, do the facts form a convenient trial unit, and the treatment of facts as a single unit conformed to the parties' expectations or business understanding or usage.

We talked about the substantial overlap between the various claims, the - the various complaints. I just also point out, Your Honor, that in terms of looking at this [10]

common nucleus of operative facts, what would the two courts be looking at?

Well, the allegations in both complaints rest on statements made by the companies to doctors or to the public about Plavix, both its efficacy and its safety profile. Well, how are -- how do drug companies communicate to health care professionals and the public and the like, in other words, those communications are what is the thing -- are the things that are at issue in both cases, those communications.

So, let's break it down. Pharmaceutical companies communicate with doctors through their sales representatives. So communications between the sales representatives and doctors in New Mexico are going to be the things that, one of the things that are going to be at issue in the Dickson case as well as this case.

So you are going to have the same witnesses, the sales reps and the doctors talking about what the sales reps allegedly said to the doctors and whether or not it was false, misleading or unfair. So that's one common nucleus of operative facts, the fact that we are going to be looking at sales reps and their promotional activities with doctors.

What's another common nucleus of operative facts here? Companies' interactions with New Mexico Medicaid, because the companies had contact with New Mexico Medicaid [11] as part of the promotional activities, those will be relevant in both Dickson and here in New Mexico.

The same people, we would talk to the same people in New Mexico Medicaid both with respect to the claims in Dickson, as well as with respect to the claims here in New Mexico.

THE COURT: Does it make any difference that New Mexico has been dismissed from that Dickson case?

MR. HARKER: Your Honor, actually New Mexico has not been dismissed from Dickson.

THE COURT: Well, there is a motion to reconsider something pending, but the operative order right now has them dismissed.

MR. HARKER: Yes. And they are dismissed, but a new complaint has been filed, including bringing allegations on behalf of New Mexico. So when you look at the pending complaint, which we have moved to dismiss --

THE COURT: Has it made new allegations that this drug was not on the approved list from the FDA?

MR. HARKER: No.

THE COURT: It's going to be hard to get around that ruling.

MR. HARKER: We think it will be very hard, but nevertheless we were under an obligation to bring this before Your Honor, because if you waive the defense of [12] claims for it initially, you have waived it entirely. So we didn't think --

THE COURT: When do you think that judge would act on the next -- I mean, I'm assuming you are going to move to dismiss again -- when do you think that judge would render a decision on that? I mean, I don't know how many times you get to replead it.

MR. HARKER: That's a good question, Your Honor. They are already up to the fourth amended complaint. The simple answer to that question is, it would just be a guess on my part how long it will take Judge Wolfson to decide the case. The motions are fully briefed.

THE COURT: Oh, they are briefed already?

MR. HARKER: Yes, Your Honor, they are fully briefed, and we are still waiting -- we are waiting for a decision. But they were only -- the briefing was only completed early this year, so in January a reply brief went in. It did take Judge Wolfson a bit of time to decide the original motion to dismiss, but I -- the signals that she is sending is that this will be less

THE COURT: Won't take quite so long?

MR. HARKER: That's right, Your Honor. I mean, essentially they have asked for a redo. The plaintiffs have asked for a redo, in large measure. And as we pointed out in our papers, what's particularly disturbing here, Your [13] Honor, is that she dismissed the New Mexico allegations.

THE COURT: I know that.

MR. HARKER: And what happened was, they got dismissed in federal court, and then the state turned around and took those allegations and brought their own case here.

Talk about forum shopping.

THE COURT: I mean, it seems to me that's appropriate. I -- if, if except for that person from Illinois refiling their case, it would seem, if your state claims get dismissed by a federal court, you come and file them in state court. That seems to me to be good.

MR. HARKER: Well, except you do have this doctrine called res judicata.

THE COURT: Well, you can argue res judicata, maybe, on the things that were dismissed, but they have other claims here under state law that were not even considered by that judge.

MR. HARKER: And our point is, is that for judicial efficiency, for fairness, for to avoid a burden on us, it would make sense if there in New Mexico -- there in Dickson, and as I said, there is a fourth amended complaint where the allegations that they are currently bringing in New Mexico are are contained in the fourth amended complaint, there is a process for them to intervene, either dismiss the case in New Jersey and say, "We are out of the [14] case in New Jersey, and we are going to bring it here in Santa Fe," a consolidated set of allegations against the companies, you know, based on Plavix and allegations about false advertising with respect to Plavix, or under the federal statute they are able to take all of their state claims and bring them in the New Jersey case.

The false -- the Federal False Claims Act gives the Court there ancillary jurisdiction over every single one of New Mexico's claims. They have a number of options, Your Honor. All we are saying is that one should not be -- but we will keep a foot in the New Jersey camp and see how we do with Judge Wolfson in New Jersey, and we'll keep a separate, but essentially the same foot in New Mexico to see how we do with Judge Singleton.

They should either cut or fish bait -- or, excuse me -- fish or cut bait, and you know, let's try the case in in New Jersey, bring all the state claims in the court in New Jersey, or dismiss New Jersey -- New Mexico out of the New Jersey case and bring the case they want to bring here in Santa Fe. They can't have their cake and eat it, too, and that's what they are trying to do.

THE COURT: Okay. I guess I better ask the other side for their opinion because we have limited time today.

MR. ALBERSTONE: And I, Your Honor, Dan Alberstone from Baron and Budd, and I do have an opinion, [15] and that opinion is contrary to Mr. Harker's opinion.

THE COURT: Are you able to answer my initial question? I really don't quite understand -- I mean, I can see how it might have been done legally, but why does this woman, the sales rep from Illinois, get to bring a case that involves New Mexico law?

First, that's my first question. My next question is, what did New Mexico know about it and why didn't they do something about it?

MR. ALBERSTONE: The first question I don't have an answer as to how or why. I do know the state at some point became aware of the claim and did not intervene in the lawsuit.

THE COURT: Okay. Were they informed? The way it would work here is they have to be informed, and then they get to choose, do we want to prosecute this, or are we going to defer and let you prosecute it? Did they go through any of those steps as to the New Mexico portion of the claim?

MR. ALBERSTONE: All I can tell you is, based on the discussions that I have had with the folks I interacted with is that a decision was made not to intervene, but I don't have that specific information for you.

THE COURT: I understand there was a decision not to intervene because they didn't intervene.

[16] MR. ALBERSTONE: Right. I don't have that information, Your Honor.

THE COURT: Why don't they do it now, if they want to bring this case --

MR. ALBERSTONE: Because they don't need to.

THE COURT: -- case go away.

* * * * *

[25] * * *

THE COURT: Okay. I found their New Mexico allegations, and it appears to be under the New Mexico Medicaid False Claims Act.

MR. ALBERSTONE: Right. That's a single claim and it's not a claim in our lawsuit.

THE COURT: Okay.

MR. ALBERSTONE: And again, the basis for this claims splitting stay request was the cases that they cited to Your Honor, and I think I have been true both to the statutes -- statute that I cited to Your Honor and the cases they cited where the decisions did not comport to what they put in their briefs.

THE COURT: Okay. And so your answer to why the State of New Mexico and the attorney general's office did not tell that New Jersey court to get lost, we want to pursue our own claim, is they didn't need to?

MR. ALBERSTONE: That's correct, although, given an opportunity I would do that.

THE COURT: Well, why don't you have the opportunity now to do that?

MR. ALBERSTONE: Well, I --

THE COURT: Seriously, I'm wondering, because [26] there is something that seems unfair about having to defend in two jurisdictions.

MR. ALBERSTONE: Let me explain something, Your Honor. You are right, and I'm going to consult with the client about that; I think that's a very fair point. But I want -- I want to put this in context about litigating in two different jurisdiction. These folks, we talked about national counsel and counsel on the line, they are litigating

in the New Jersey federal court in multi-court litigation, involving state's attorneys general from Virginia, Mississippi, Louisiana, Hawaii, which I also represent, I just represent Hawaii, and hundreds if not thousands of personal injury lawsuits.

This is a spec on the litigation that they are involved in back east, and all relating to the same issues. So you know, there is not much of a burden or inconvenience -- you shouldn't be left with the impression these folks are just litigating in --

THE COURT: I'm not thinking they are sole practitioners having to run around from New Jersey to New Mexico and Hawaii and everywhere.

MR. ALBERSTONE: Fair enough. What I just meant to say was, there is a lot of lawsuits relating to the same facts, this isn't any burden on them. But in any event, I think we are legally correct, that we're allowed to proceed [27] on the claims we have asserted in this court based on the case law I have discussed with the Court.

THE COURT: Well, as I understand -- maybe it's different for this kind of a case that they brought in New Jersey, but in the qui tam actions or FATA actions, the relator is representing the State of New Mexico. I mean, if the attorney general declines to intervene and prosecute it himself, then they are representing the State of New Mexico.

So why isn't that the case here in New Jersey? You've got somebody already representing the State of New Mexico, and so what you are saying is because you have different theories of recovery, you get to bring -- you get to do it here, also?

MR. ALBERSTONE: There is two issues. One is, they are different claims that are being brought, some of

which can only be brought by the state attorney general, that's number one. And Number 2 is, the state attorney general has made the decision that in its consumer protection cases it wants to bring its consumer protection cases in state court in the state of New Mexico.

THE COURT: I understand that. I just wish they would have gotten out of New Jersey.

MR. ALBERSTONE: And I'm going to consult with the client about that. It's a fair point, like I said, from 1 the very beginning. And again, you've got to look at the [28] context of that relator case, here is somebody who is doing a shotgun approach from Illinois representing -- purporting to represent 24 or 25 different states.

THE COURT: That's not --

MR. ALBERSTONE: I just threw a number out, frankly.

THE COURT: Okay.

MR. ALBERSTONE: Okay. Thank you, Your Honor

THE COURT: You wish to respond?

MR. HARKER: I will say, you know, I'm glad to answer your questions. I think you kind of got to the heart of and you understand how unfair this is and why we are doing this, why is the state doing this.

One thing I never heard Mr. Alberstone say about the Dickson case was that the state wasn't going to take any money that Miss Dickson was able to win for it in that Dickson case. So, you know, he can say all he wants about the state can consent and so on --

THE COURT: Isn't Dickson, it appears more likely to me, but if she wins money under that theory that she's pleaded, which I'm forgetting again the name of it.

MR. HARKER: Medicaid False Claims Act.

THE COURT: Yeah, Medicaid False Claims Act, isn't it possible that here in New Mexico they would recover money from your client for violations of different statutes?

[29] MR. HARKER: These statutes are so closely interrelated, Your Honor, in New Mexico, the Fraud Against Taxpayers Act, the Medicaid False Claims Act, the Medicaid Fraud Act, that, I mean, that would be obviously something we would have to look at, but one of the harms that the state that had been announced in terms of the claims splitting rule is to avoid the burden, a, the burdens of defending cases in different places, as well as the possibility of inconsistent results and also double judgments, and that's what we are concerned about.

The state, in fact -- the state did in fact consent. When you look at the statute, whether it was the attorney general or the human services department, the statute -- the statute that we cited to you does require the state to consent to the relator going forward without intervention.

The state has enormous power over the relator's case, which I will say this, the relator in that case was represented by the Grace Fall firm in Texas, so she might be in Arkansas, but believe me, she is very capably represented there. But the New Mexico statute, what does it say --

THE COURT: She might be capably represented, but really, what does she know -- I mean, what does she even care about New Mexico compared to the other stuff she is arguing about.

[30] MR. HARKER: The thing is, Your Honor, the reason why, and, you know, we are focused on the fact that they have brought a separate count, a different count than in New Mexico. I don't know why New Mexico didn't bring a Medicaid False Claims Act count. Perhaps it was to be able to maintain -- they knew they were claims splitting, and they wanted to be able to maintain as much distance between the two cases as possible.

THE COURT: Yeah, but --

MR. HARKER: I was going to say, but under New Mexico law, the fact, the status or the test is, same parties and same claims. It has nothing to do with the fact that the counts are different. That is the law in some places, like in Hawaii, it's important whether or not the counts line up. But here in New Mexico, case after case, either for res judicata purposes or for purposes of claims splitting say that the legal theories that are used are irrelevant to the idea of whether or not the claims are improperly split.

THE COURT: Not if the Court in the first case doesn't have jurisdiction over the claims that they want to raise in the second case.

MR. HARKER: And Your Honor, let me address that, if that's of concern to you.

THE COURT: Well, it is.

[31] MR. HARKER: Under the false -- and I didn't hear -- I mentioned this earlier, and I didn't hear Mr. Alberstone dispute this, but under the -- under 31-USC-3732, that's the part of the False Claims Act, it specifically says that the federal court has ancillary jurisdiction over any state claim that the state wants to bring.

So they can bring those claims, the claims that they are saying that Dickson couldn't bring, Miss Dickson

couldn't bring, they can take those claims -- they can just basically transport their current case and file it in New Jersey. They don't want to do that.

THE COURT: Right, they don't want to do that. They want their case tried in New Mexico, which is certainly understandable.

MR. HARKER: But they can't have a foot in New Jersey and also have a foot in New Mexico, and that's the problem that we have, Your Honor.

THE COURT: But you could, if you just use the jurisdiction analysis, then they could have a foot in both states, because the one place, that relator cannot bring claims that have to be brought by the attorney general, and the attorney general isn't bound by her selection of forum.

MR. HARKER: No, but --

THE COURT: On those claims that only the [32] attorney general can bring.

MR. HARKER: Then what they need to do is they need to get out of New Jersey.

THE COURT: Well, I couldn't agree with you more, but I would probably say that to anybody.

MR. HARKER: But aren't we talking -- we are sort of talking about a classic situation of claims splitting. I think you have seen how much overlap there is between the two cases. The attorney general can intervene. The attorney general can come in and dismiss Miss Dickson, take over the case in New Jersey, bring all of their claims, and all we are saying, Your Honor, is they shouldn't be able to have two bites at the apple.

And the way that this went down, as I said before, Miss Dickson loses the New Mexico claims and suddenly the attorney general brings them here, resurrects them.

THE COURT: Again, I think that's perfectly appropriate, but what can I say?

MR. HARKER: I think, again, once assuming that Judge Wolfson follows what she did the first time and doesn't change course and dismisses New Mexico's claims from the Dickson case, I think then we will have the different argument about res judicata. Right now we are talking about claims splitting. At that moment we will have a discussion [33] about res judicata, and we will have an opportunity, both Mr. Alberstone and myself, to fully brief the issue that we are talking about.

THE COURT: The res judicata?

MR. HARKER: Yes, in the context of res judicata.

THE COURT: Okay. Thank you.

MR. HARKER: Anything else, Your Honor?

THE COURT: Not on this issue. I think that I have a fair amount of discretion in the matter of whether or not a case should be stayed in favor of previously filed litigation, and I have to say, I don't like the idea of the New Mexico related claims being litigated in two places at once.

Frankly, this great inconvenience claim doesn't really impress me as to these defendants, and they are perfectly capable of litigating in any number of jurisdictions at once, but I am concerned about the possibility of inconsistent judgments, and this bothers me that New Mexico is involved in both the New Jersey cases and the New Mexico case. So I'm going to stay this case for a period of up to two months to give the attorney general the opportunity to dismiss the case in New Jersey on a voluntary

dismissal basis and consolidate everything that can be brought in the New Mexico case.

At the end of two months if that hasn't been [34] done, then I will revisit what to do with the current case. That might also give Judge Wolfson the opportunity to rule on the most recent motions to dismiss, and as far as I'm concerned, once those motions to dismiss are granted, it is more than appropriate for the attorney general to file in New Mexico, and we can fight about whether or not there is any res judicata effect with those dismissals.

But I'm going to stay this case for a period of two months, and consequently I know you told me I should now act on the 12(b)(6), but I'm not going to do that. I'm going to wait until we see where we stand because I think it will be easier if we have a better, more complete concept of where this litigation stands.

* * * * *

APPENDIX H

STATE OF NEW MEXICO
COUNTY OF SANTA FE
FIRST JUDICIAL DISTRICT COURT

Case No. D-101-CV-2016-02176

STATE OF NEW MEXICO, ex rel.
HECTOR BALDERAS, ATTORNEY GENERAL,

Plaintiff,

v.

BRISTOL-MYERS SQUIBB COMPANY,
SANOFI-AVENTIS U.S., LLC,
SANOFI US SERVICES INC., formerly
known as SANOFI-AVENTIS U.S. INC.,
SANOFI-SYNTHELABO INC., and
DOE DEFENDANTS 1 to 100,

Defendants.

ORDER ON MOTION TO STAY PROCEEDINGS

This matter was originally heard on Defendants' motion to stay proceedings based on the doctrine against claim splitting. At the hearing on the motion on March 1, 2017, the Court expressed concern with the possibility that there could be conflicting judgments if the present case were pursued while a case raising claims on behalf of New Mexico under the New Mexico False Claims Act was pending in New Jersey. While the claims in the New Jersey case were not brought under the same legal theories, the claims in both cases appeared to arise out of common facts. The Court entered a stay to allow the State to take some action that would alleviate the danger of

inconsistent judgments. By letter the State informed the Court that it had taken no action vis-à-vis the New Jersey case. See Exhibit 1. The defendants responded by letter requesting that the stay be continued. See Exhibit 2. The Court having considered the matter has determined that the stay should be continued until the New Jersey case is resolved or the State of New Mexico is no longer included in its claims.

IT IS SO ORDERED.

Sarah M. Singleton,
District Court Judge

* * * * *

APPENDIX I

FIRST JUDICIAL DISTRICT COURT
COUNTY OF SANTA FE
STATE OF NEW MEXICO

STATE OF NEW MEXICO, ex rel,
HECTOR BALDERAS, ATTORNEY GENERAL,

Plaintiff,

vs.

BRISTOL-MYERS SQUIBB COMPANY,
SANOFI-AVENTIS US LLC
SANOFI US SERVICES, INC., formerly
known as SANOFI-AVENTIS US INC.,
SANOFI-SYNTHELABO INC., and
DOE DEFENDANTS 1 TO 100,

Defendants.

D-101-CV-2016-2176

FINAL TRANSCRIPT OF PROCEEDINGS

On the 3rd day of November 2017, this matter came on for hearing on MOTIONS before the HONORABLE SARAH SINGLETON, Judge of the First Judicial District, Division II, State of New Mexico.

The DEFENDANTS were represented by Counsel of Record, TIM HOLM and DREW A. HARKER.

The PLAINTIFFS were represented by P. CHOLLA KHOURY and DANIEL ALBERSTONE.

At which time the following proceedings were held:

[2] November 3, 2017

(In open court.)

THE COURT: We are here today in the matter of State of New Mexico, ex rel Hector Balderas, Attorney General, versus Bristol-Myers Squibb Company and others. It's D-101-CV-2016-02176.

First of all, could I have people enter their appearances on behalf of the plaintiff.

MR. ALBERSTONE: Yes, Your Honor. Good morning. Dan Alberstone of Baron and Budd on behalf of the plaintiff, State of New Mexico.

MS. KHOURY: Cholla Khoury with the Office of the New Mexico Attorney General.

THE COURT: Thank you very much. Is any other counsel appearing for the plaintiff?

MR. ALBERSTONE: No, Your Honor.

THE COURT: Thank you. Then let's go to the defendants.

MR. HOLM: For the defendants, Your Honor, my name is Tim Holm from Modrall Sperling. With me is Drew Harker from Arnold & Porter who has been admitted pro hac and will be presenting argument along with me this morning.

Also at counsel table is Said Saba, also from Arnold & Porter who will not be presenting argument. On the telephone just listening in, but not presenting argument, [3] are Daniel Dovdavany, associate general counsel for Sonofi US and Cecily Williams Henson, in-house counsel for Bristol-Myers Squibb.

* * * * *

[4] THE COURT: All right. We will do res judicata first.

MR. HARKER: Good morning, Your Honor.

THE COURT: Good morning.

MR. HARKER: My name is Drew Harker for the defendants. This case should be dismissed on res judicata grounds. The State's claims are based on the same facts at issue in the Dickson case which we talked to you about last March that was pending in the federal district court in New Jersey.

After that hearing, Your Honor stayed this case, the New Mexico case here in Santa Fe, and in doing so you expressed concern that both cases arise from defendant's alleged deceptive labeling and promotion of Plavix.

In your order granting the stay, you said that you were, quote, "Concerned about the risk of inconsistent judgments and about the fact that plaintiff has not taken any steps to consolidate its claims in a single jurisdiction."

And in your order you also emphasize that, I'm quoting, "Plaintiff's complaint and the claims asserted on plaintiffs' behalf in Dickson share some common operative facts."

And you stayed this case in order to give the State the, quote, "The opportunity to cause the dismissal of [5] the Dickson action on a voluntary dismissal basis or otherwise consolidate the Medicaid False Claims Act cause of action brought in Dickson."

This was in March, Your Honor. Subsequent to your order, the State made no efforts to consolidate its claims in one court. And in reaction, in response to the State's request that you lift the stay that you had entered, which was due to expire on May 1, you rejected that, and in fact, extended the stay.

And in extending the stay, you said, "While the claims in the New Jersey case were not brought under the same legal theories, the claims in both cases appear to arise out

of common facts," and you also expressed a concern about the risk of conflicting judgments. Still, the State made no effort to consolidate its claims.

Well, it's time to pay the piper, Your Honor. Dickson has now been decided in New Jersey, as you know, and it dismissed for a second time the New Mexico claims brought in that court.

THE COURT: Could I ask a question about that?

MR. HARKER: Absolutely.

THE COURT: I want to make sure I'm reading the Dickson case correctly. It seemed to me that there was a claim that dealt with how the drug got to be on the list of preferred drug -- drugs, and that on that one he allowed [6] her leave to amend. Now, she didn't do that, but he didn't dismiss that one.

MR. HARKER: There was two Dickson opinions, Your Honor. The Dickson III opinion was in 2015. The second opinion was in June of 2017.

THE COURT: I think that's the one I'm talking about.

MR. HARKER: And that was a final judgment. That was, as a matter of law, the judge ruled that Ms. Dickson's allegations with respect to placement of Plavix on the formulary did not state a cause of action under the False Claims Act. There was no opportunity to amend.

THE COURT: Hang on just a minute. I'm looking at your Exhibit A, and -- June 27, 2017 and I'm looking at what was the printout Page 14.

And it says, "Accordingly, defendant's motion to dismiss the formulary allegations as law of the case is denied, and I will now turn to the merits of the claim."

And so then you are saying on the merits he dismissed that, too, as not stating a claim.

MR. HARKER: That's correct, Your Honor. Essentially Dickson sought in the fourth amended complaint to restate her formulary allegations that the Court had dismissed in Dickson III. And we had argued, since Dickson III dismissed those claims, the law of the case was she [7] didn't have to get to the merits of those claims in the fourth amended complaint.

As you see from her opinion she rejected our argument that it was the law of the case and then dealt with the issue on the merits, and concluded that, on the merits, and as a matter of law, the allegations about placement of Plavix on the formulary did not state a claim under both federal law as well as state law. May I go on?

THE COURT: Yes.

MR. HARKER: So as we have outlined in our briefs which I will summarize this morning, res judicata applies to bar New Mexico's complaint here for three reasons, for all three elements of res judicata on that.

First, the parties are the same. The claims share a, quote, "Common nucleus of operative facts," as you already indicated in your two orders, and Dickson was a final decision on the merits.

So let's talk, first of all, about the State being a party in the Dickson case. So we will talk about concepts like privity and real party in interest because those are important in terms of understanding why our position is, is that -- why our position is, is that New Mexico is in the Dickson case.

So because basically our position is, is that New Mexico and Ms. Dickson were in privity in connection with [8]

that case in New Jersey, and that New Mexico remained the real party in interest in that case.

* * * * *

[27] * * *

THE COURT: Dickson's counsel, is that who we are talking about?

MR. ALBERSTONE: Correct, Dickson's counsel, and they weren't cooperative, the relator's counsel.

Now, I had a previous history with Judge Wolfson in the Dickson case because I also represent the State of Hawaii. And earlier on, months ago, if not even a year ago now, I appeared before Judge Wolfson because there was an issue that arose with the State of Hawaii with respect to extricating itself from that multidistrict litigation, and the facts of it aren't important.

But at the time what happened was, Judge Wolfson was resistant to that, but ultimately decided that she had no choice, because we were right, and allowed the State to extricate itself.

But then what she told me was:

"I don't understand why you don't want to be in this courthouse," and she was trying to get me to convince the State of Hawaii to remain in that case. I explained to [28] her the reasons why the State wanted to have its case prosecuted, after having it removed by defendants to federal court and remanded back to state court, why the State wanted it in state court.

So she said:

"Well, go back and talk to your clients," and the clients didn't want to move it.

And you have to understand what the procedural status of this case was. There was a motion to dismiss pending, fully briefed, under submission, fourth amended complaint. The defendants wouldn't agree to move it here, and I'm not complaining that they wouldn't, but they wouldn't.

I knew that there was zero chance that this judge was going to allow us to intervene in this case because the requirement of a showing of good cause. And there was no circumstance that I could understand that I went in there, tried to intervene for purposes of removing it, when she had under submission a motion to dismiss under fourth amended complaint.

And I'm not complaining about that, I'm not saying she is wrong, but that's the reason we didn't go in. We didn't have the defendant's cooperation. We didn't have the relator's cooperation. We would have been hard-pressed to show good cause to intervene. There was no chance of its [29] being removed or dismissed by the State.

Now, folks can agree or disagree with that decision, but I'm being upfront with the Court as to what happened.

THE COURT: At some point, if not by you all, initially when the State decided not to intervene in that action, they had to think that whatever happened in this Dickson on the Medicaid False Claims Act case was going to be binding on the State.

MR. ALBERSTONE: I can't conjecture as to what they were thinking, but I understand the Court's thinking.

THE COURT: Legally, I'm not talking about their internal processes, I'm just saying, as a legal proposition, they must have confronted that.

MR. ALBERSTONE: If the case proceeded past the pleading stage, which is what I want to focus on, if I can, I think the defendants are wrong on the facts, wrong on the law, and I think they mischaracterize certain aspects of the law with respect to this.

US versus Eisenstein with respect to this issue was dicta. It was thrown in there, and it wasn't necessary for the Court's decision. The Peterson Court also cited to the Eisenstein decision, but again, it was dicta. But it doesn't matter, because there is other cases that we have cited, that counsel didn't discuss with you when he was up [30] here, that shed light on what needs to happen here.

And we first start with what the Court already focused on, which was Judge Wolfson's decision in Dickson. And there was no question that the case was dismissed, not based on the merits of the case, but based on the failure to meet the pleading standards under 9(b).

And what Judge Wolfson said, as generally the Court pointed out, quote:

"Here as discussed below, the Court finds the imposition by the Supreme Court in Escobar of a heightened pleading standard for materiality under the FCA to be dispositive of relator's allegations in the fourth amended complaint.

"As such, other than observing that the Escobar decision constitutes a supervening change in law with regard to the materiality element, the Court need not decide whether the pleading standards or elements of the FCA or for pleading fraud with particularity under 9(b) have been affected by that decision."

The Court decided it based on failure to meet materially under Escobar. It's a pleading issue. It never got

past the pleading stage. We have cited a number of cases, Your Honor, which are critical to this Court's decision.

Williams versus Bell Helicopter, Fifth Circuit, [31] 2005 case, in which the Court found:

"The government asserted the district court erred in dismissing the complaint against the US with prejudice, specifically, the government argued its statutory right should not be foreclosed when a qui tam action is dismissed not on the merits, but because of a deficient complaint under Rule 9(b).

"The record is devoid as to why the government did not intervene. Given the Rule 9(b) deficiencies, the government may have determined the cost associated with the proceeding based on a poorly-drafted complaint outweighed any anticipated benefits. While the government could have opted to intervene and amend, it is not the Court's duty to speculate as to the costs and benefits associated with such a strategy."

The Court goes on:

"By essentially requiring the government to intervene in order to avoid forfeiture of any future claims against the defendant, private parties would have the added incentive to file FCA suits lacking in the required particularity knowing full well that the government would be obligated to intervene and ultimately fill in the blanks of a deficient complaint.

"To avoid such perverse incentives, the Court found that the district Court abused its discretion in [32] dismissing the claims as to the US with prejudice after holding that the qui tam complaint failed to meet the heightened pleading standards of Rule 9(b)."

The Court, importantly, Your Honor, found the case was distinguishable from Schimmels, which the

defendants cite, where the government was found to have tacitly participated.

I want to talk a moment just about Schimmels, because in that case, in a footnote, the Court -- the Court explained why it found there to be participation.

What the Schimmels Court said was, listen, two things happened here. The government lawyers showed up to basically every hearing that the qui tam relator had. So there was that participation by showing up to every hearing.

There was also participation, the Court found, because the State had filed its own motion in the bankruptcy court to challenge the discharge of the debtor and asked the Court to hold their separate motion under abeyance until the Court had decided the relator's complaint.

So based on that, the Schimmels Court said there was tacit participation in the case. And what the Court went on to say is, noting again, referring to the Restatement (Second) of Judgments, Section 37, the comments, 1982, quote:

"Unless the official party in whose name the [33] action is brought or defendant has some participatory or supervisory authority in the action, he is not concluded by the judgment."

There is no evidence, Your Honor, and it just didn't happen that the State of New Mexico participated in any fashion in connection with the Dickson case.

THE COURT: Are you suggesting if Ms. Dickson had won and recovered money, that the State wouldn't have been entitled to get the money, or at least the bulk of it?

MR. ALBERSTONE: I'm not suggesting that at all. I'm suggesting that as a result of the fact it never got past the pleading stage and there are two other cases that we cited that follow the Williams case. One is US -- it was cited in our papers -- US versus Health Management, a 2014 district court case in Florida.

The Court found, quote:

"In a case such as this, dismissal with prejudice to the government would be inappropriate because the dismissal was based on the relator's failure to comply with the heightened pleading requirements of Rule 9(b), a matter unrelated to the merits of the claim. If the Court were to accept defendant's position, the government would essentially be compelled to intervene in FCA suits and fill in the blanks of a defective complaint in order to protect its rights."

[34] And Williams was also followed in a 2011 case, Southern District of New York, again cited in our papers, US versus Quest Diagnostics. And so, like I suggested earlier, Your Honor, Eisenstein is at best is a general rule, but it didn't address the fact, as these other cases did and where these other Courts refused to follow -- refused to follow the Eisenstein ruling because they said here, when you are not -- when you are dealing the pleading stage, and the relator is unable to state a cause of action, that shouldn't impact the State.

In addition, Your Honor, as the Court noted, we have not brought a False Claims Act; we haven't done that, so we are not seeking to relitigate that claim at all.

And just as a side note, Your Honor, I do think that Judge Wolfson did get it wrong because what Escobar talks about is something a little different than what occurred.

The relators in Dickson, as we have here, have suggested that, had the State known, had the State known that they were lying, then the defendants would not have received all of this money. They would not have approved it.

The mere fact, for example, that the State that a drug gets on the PDL, the formulary, and gets paid automatically, just talks about the system, because how [35] could the State realistically evaluate each representation every time, as a matter of practicality, each time a prescription is put in and reimbursement is being sought.

But we did allege here, as they did allege in Dickson, that had the State known, these claims wouldn't have been paid. What they are complaining about is the system we had in place in terms automatically paying it.

It doesn't mean that, through this automation, if at some point the State became aware of it, that they wouldn't pay it. So the allegation is in there. Whether the facts prove that or not later on in terms of whether that's accurate or whether there is some other facts, we are going to learn that in discovery.

The other issue I wanted to bring up is this whole idea of a party being foreclosed out, and there was a citation of a number of cases. But the Potter versus Pierce case that the defendants cited in their papers, in that case the Court expressly found that res judicata only applies if the claim reasonably could and should have been brought during the earlier proceeding by the party. By the party, not the relator -- excuse me -- not the party in privity, but the party to the case.

And so at least other than a FATA case, the party, the relator, had no statutory right to raise the Medicaid -- the Fraud Against -- I forgot what it's called [36] now, I apologize. But the other statutory claims, including Unfair

Practices Act, Fraud Against Taxpayers is the one they could have brought, and there is one other common-law claims, the relator had no right to bring those causes of action.

So the party, the relator, because we do distinguish between parties and those in privity, in fact some of the cases the defendants cite distinguish those two. So at the end of the day, Your Honor, in terms res judicata, it's just not there. Is there a common nucleus of operative facts? I think there are in part, not in whole. For example, we have alleged this variability of response claim that was dropped in an earlier -- voluntarily dropped by the relator --

THE COURT: That's the people who don't metabolize?

MR. ALBERSTONE: Correct, which is part of our case. That wasn't the subject of Judge Wolfson's ultimate decision in the case. So there are differences, but I'm not going to argue that they -- the common nucleus of facts aren't there, but they don't satisfy the other element in terms of proving this was on the merits.

And they raise this big issue of trying to shoehorn this into the merits when it wasn't on merits, as I read from Judge Wolfson's order. So on res judicata, Your [37] Honor, unless the Court has any questions, I think this case should proceed.

THE COURT: All right. Thank you. Do you want to briefly respond?

MR. HARKER: Yes, Your Honor, I would briefly respond. First of all, let me start with something that Mr. Alberstone talked about, taking exception to something that Judge Wolfson had decided.

So, you know, with respect to whether or not alleged false statements to the formulary constituted a violation of the law, Judge Wolfson found what she found. She clearly found that misstated a claim. Mr. Alberstone says he disagree with that. Back to your order, Your Honor, about the risk of inconsistent judgments presented front and center with Mr. Alberstone's admission.

The second thing is, let's step back for a second, okay. The Dickson added that -- Ms. Dickson added New Mexico claims in 2011, and the State was aware of those claims; they were served with the complaint. So they knew that New Mexico was in play in New Jersey.

But not only that, what's important to recognize so at least as of 2011, for six years they knew that Dickson was at play, that New Mexico was in play in Dickson in New Jersey, and so they could have impact on them. But importantly, the chronology in this case, let's look at the [38] chronology in this case.

In this case the State filed its complaint here on September 14, 2016. We moved to dismiss, including on claims splitting, slash, res judicata grounds, on November 28, 2016. We didn't move to dismiss Ms. Dickson's complaint in, the fourth amended complaint, in New Jersey until two months later, January 30.

So they had -- at a minimum they had six years of notice, but they had two months where they were clearly on notice about the problem with the overlap between the two cases, and yet they did not nothing. They are talking about the idea that, well, by the time they started looking at this, the motion to dismiss in Dickson was fully briefed.

Okay, I don't -- that may be the case, but the problem is, is that they had two months before we filed the motion to dismiss to do something with respect to Dickson.

THE COURT: Well, before you filed the motion to dismiss the fourth amended complaint, I think you had filed quite a few before that, so they knew that was coming.

MR. HARKER: Absolutely. Absolutely. But my point is, is that --

THE COURT: And they also, I think they are absolutely right, at least it's been my experience with federal judges who have multidistrict cases, they want everybody to be there. They don't want anybody out there [39] outlying their case.

MR. HARKER: Your Honor, if I might just take exception to that for a second in terms of Ms. Wolfson, because if you look at the history of this, Mr. Alberstone mentioned Hawaii, and there was an issue of not about being in -- Hawaii being in the MDL, but about whether or not the special master appointed there, which Hawaii had earlier agreed would be part of -- would decide Hawaii discovery issues, and then when Mr. Alberstone came in, that agreement no longer was in place.

But so -- so in terms of that point, Mr. Alberstone has already said that Ms. Wolf -- Judge Wolfson said:

"Okay, Hawaii, you don't want to be part of the discovery resolution process in the MDL, that's fine."

But more importantly, Mississippi and West Virginia are two other state AG cases. We removed those to federal court. She said:

"They don't belong in federal court; they should go back to state court."

So this is not really a judge who I think you could say was inquisitive in terms of wanting everything in her court.

The final thing I will say is that the State has been in control. They could have moved to dismiss Dickson [40] even without any -- even over the objection of the relator.

In fact, the statute says that the State has the unfettered right -- the unfettered right to dismiss -- to move to dismiss a private cause of action. The State could have done it in 2011, the State could have done it 2016, and the State could have done it in 2017.

You put your finger on it, Your Honor, when you asked Mr. Alberstone when you said:

"Are you saying you wouldn't want any of the recovery in New Jersey?"

And he candidly said, no, that was not what he was saying. They were basically trying to play both sides of the fence, and Courts in New Mexico have rejected that.

* * * * *

APPENDIX J

STATE OF NEW MEXICO
COUNTY OF SANTA FE
FIRST JUDICIAL DISTRICT COURT

STATE OF NEW MEXICO, ex rel.
HECTOR BALDERAS, ATTORNEY GENERAL,
Plaintiff,
v.
BRISTOL-MYERS SQUIBB COMPANY,
SANOFI-AVENTIS U.S., LLC,
SANOFI US SERVICES INC., formerly
known as SANOFI-AVENTIS U.S. INC.,
SANOFI-SYNTHELABO INC., and
DOE DEFENDANTS 1 to 100,
Defendants.

Case No. D-101-CV-2016-02176

DEFENDANTS' SUPPLEMENTAL MEMORANDUM REGARDING DEFENDANTS' MOTION TO DISMISS PLAINTIFF'S COMPLAINT FOR DECLARATORY RELIEF, DAMAGES AND CIVIL PENALTIES

* * * * *

[Defendants' Memorandum and Exhibits A-C omitted]

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EXHIBIT D

***State of N.M. ex rel. Balderas v. Bristol-Myers Squibb Co.*, No. D-101-CV-2016-02176**

Comparison of the core allegations in the State of New Mexico's Complaint with the allegations in Relator Elisha Dickson's pleadings in *United States ex rel. Dickson v. Bristol-Myers Squibb Co.*, MDL No. 13-2418 (D.N.J.)

A. Section I.A. of the factual allegations section of the State's Complaint: **"Failure to Disclose Plavix's Diminished Effectiveness in a Significant Percentage of the Patient Population."** New Mexico Compl. ¶¶ 29-47.

New Mexico Complaint	***Dickson* First Am. Compl. ("Dickson 1AC")**
"On March 25, 2010, Defendants added a black box warning to Plavix's label that states that Plavix does not become effective until it is metabolized into its active form by the CYP2C19 liver enzyme. Individuals with particular CYP2C19 genotypes are CYP2C19 poor metabolizers. The black box warning . . . cautions	"On March 25, 2010 FDA added a black box warning to the Plavix prescribing information." Dickson 1AC, ¶ 29. 'The black box warning advised that Plavix does not have its anti-platelet effects until it is metabolized into its active form by the liver enzyme, CYP2C19." *Id.* ¶ 30. "[W]hen a patient who is a CYP2C19 poor

New Mexico Complaint	***Dickson* First Am. Compl. ("Dickson 1AC")**
that Plavix has diminished effectiveness in patients who are CYP2Cl9 poor metabolizers . . . ." New Mexico Compl. ¶ 29.	metabolizer takes Plavix, that patient receives no anti-platelet protection." *Id.* ¶ 32.
"It is believed that a significant percentage of the patient population in New Mexico consists of CYP2Cl9 poor metabolizers." New Mexico Compl. ¶ 30.	"It is estimated that 2 percent to 14 percent of the U.S. population are poor metabolizers, and people of Asian and African ancestry have a greatly increased prevalence of poor CYP2Cl9 metabolizer status." Dickson 1AC ¶ 32.
"The black box warning added in March 2010 also states that patients who are CYP2Cl9 poor metabolizers treated with Plavix have higher cardiovascular event rates than patients with normal CYP2Cl9 function." New Mexico Compl. ¶ 31.	"Researchers have found that patients who are CYP2Cl9 poor metabolizers have a 3.58 times greater risk for major adverse cardiovascular events such as death, heart attack, and stroke." Dickson 1AC ¶ 33.
"[S]ince at least March 1998, 12 years before the black box warning was added, ***Defendants knew or . . . should have known that Plavix has***	"BMS/Sanofi has known about the diminished anti-platelet effect of Plavix for patients who are poor CYP2Cl9 metabolizers since at least 2003 or

New Mexico Complaint	***Dickson* First Am. Compl. ("Dickson 1AC")**
diminished or no effect on patients who are CYP2C19 poor metabolizers. . . . Defendants, however, failed to disclose that information in order to protect Plavix's sales and revenues." New Mexico Compl. ¶ 32 (emphasis added); see also *Id.* ¶¶ 3, 103.	earlier." Dickson 1AC ¶ 27. "***Defendants had full knowledge that Plavix provided little to no anti-platelet protection for poor CYP2C19 metabolizers*** yet failed to amend their label to reflect this." *Id.* ¶ 49 (emphasis added); *see also Id.* ¶ 291.
"[S]ince at least 2003, Defendants knew or by the exercise of reasonable care should have known that Plavix has diminished or no effect on patients who are also taking drugs that are CYP2Cl9 inhibitors. … Defendants, however, failed to disclose that information in order to protect Plavix's sales and revenues." New Mexico Compl. ¶ 33.	"From 2003 onwards, Defendants had full knowledge that the concomitant use of Plavix with strong or moderate CYP2Cl9 inhibitors would sever[e]ly compromise, if not eliminate, Plavix's anti-platelet activity, yet failed to amend their label to reflect this information." Dickson 1AC ¶ 48.

B. Section I.B. of the factual allegations section of the State's Complaint: **"False, Deceptive, and Unfair Superiority Claims."** New Mexico Compl. ¶¶ 48-60.

New Mexico Complaint	***Dickson* Fourth Am. Compl. ("Dickson 4AC")**
"Defendants ignored, concealed, and minimized clinical trial data and other information showing that Plavix is only as effective as–or in some cases even less effective than–aspirin in treating such patients, and that Plavix has a higher chance of causing gastrointestinal bleeding and other complications. Despite that information, ***Defendants falsely and misleadingly marketed Plavix as being more effective and safer than aspirin***." New Mexico Compl. ¶ 4 (emphasis added). "[S]ince March 1998, Defendants have sought to increase Plavix sales and market share by making ***false and misleading superiority claims about Plavix relative to aspirin….*** Aspirin costs approximately	"Plavix costs approximately $4.00 per pill, whereas aspirin costs approximately $0.04 per pill. ***This action arises out of BMS/Sanofi's practice of promoting Plavix as a superior drug to aspirin*** … and charging approximately 100 times more for Plavix . . . , when in fact Plavix is no more effective than aspirin for certain indicated usages." Dickson 4AC ¶ 3 (emphasis added). "BMS and Sanofi have knowingly participated in a comprehensive scheme to defraud federal and state governments by ***illegally and deceptively promoting Plavix as superior to aspirin…."*** *Id.* ¶ 15 (emphasis added).

New Mexico Complaint	*Dickson* Fourth Am. Compl. ("Dickson 4AC")
$.04 per pill, while Plavix costs approximately $4.00 per pill." *Id.* ¶ 48 (emphasis added); *see also Id.* ¶¶ 137, 156, 170.	
"The efficacy and safety of Plavix and aspirin for treatment of patients at risk for ischemic events were studied in the [CAPRIE] clinical trial, the results of which were published in 1996. The CAPRIE trial studied 19,185 patients who were divided into three subgroups of approximately 6,300 patients. The three subgroups were respectively comprised of: (1) patients who experienced a recent stroke; (2) patients who experienced recent myocardial infarction; and (3) patients who experienced symptomatic [peripheral arterial disease]. Half of the patients in each subgroup were given 325 mg of aspirin once daily and the other half were given 75 mg of Plavix once	"Plavix is indicated for treatment of patients who have recently suffered from stroke. Plavix's indication for patients with recent strokes was obtained based on the [CAPRIE] clinical trial. The CAPRIE trial enrolled 19,185 patients with approximately 6,300 patients in each of three different subgroups. The three subgroups included (a) patients who experienced a recent stroke, (b) patients who experienced recent myocardial infarction…, and (c) patients who experienced symptomatic peripheral arterial disease…. In each subgroup, half of the patients were given 325 mg of aspirin once daily and the other half were given 75 mg of

New Mexico Complaint	***Dickson* Fourth Am. Compl. ("Dickson 4AC")**
daily." New Mexico Compl. ¶ 49.	Plavix daily." Dickson 4AC ¶ 167.
"The primary objective of the [CAPRIE] study was to compare the rates of ischemic stroke, myocardial infarction, and vascular death between patients taking Plavix and patients taking aspirin." New Mexico Comp1. ¶ 49.	"The primary efficacy endpoint for the [CAPRIE] trial was the combination of ischemic stroke, MI, or vascular death." Dickson 4AC ¶ 168.
"The CAPRIE trial results showed an absolute risk reduction of only 0.5%. In other words, out of every 1,000 patients, a mere 5 patients experienced a benefit from treatment with Plavix in comparison to treatment with aspirin. ***While Plavix showed a slightly significant relative risk reduction of 8.7%, that figure was based in large part on the results in the PAD subgroup, which demonstrated a relative risk reduction of 23.8%***. In the subgroups comprised of patients who had a recent stroke or myocardial infarction, the trial	"In the CAPRIE trial, ***Plavix demonstrated a marginally significant 8.7% relative risk reduction*** of the primary endpoint compared to aspirin. The absolute risk reduction was 0.5%, meaning that for every 1,000 patients treated with Plavix only five patients benefited from Plavix treatment as compared to aspirin treatment." Dickson 4AC ¶ 168. "***The CAPRIE composite data was driven primarily by the PAD subgroup, which showed a relative risk reduction of 23.8%*** in

New Mexico Complaint	***Dickson* Fourth Am. Compl. ("Dickson 4AC")**
results did not show that Plavix had a statistically significant risk reduction; in fact, ***aspirin had a greater relative risk reduction than Plavix in patients who had a recent myocardial infarction***." New Mexico Compl. ¶ 50 (emphases added).	the primary endpoint. However, in the recent stroke and recent myocardial infarction subgroups, CAPRIE demonstrated that there was no statistically significant reduction in the primary endpoint for patients taking Plavix as compared to patients taking aspirin. Indeed, ***in the case of aspirin, even though no statistically significant reduction existed favoring aspirin over Plavix*** **for recent myocardial infarctions, the study concluded that the trend favored aspirin over Plavix.**" *Id.* ¶ 169 (emphases added).
"[N]otwithstanding [the CAPRIE] results, since Plavix's product launch in March 1998, Defendants have falsely and misleadingly marketed Plavix as being superior to aspirin in treating stroke and heart attack patients in order to take market share away from aspirin	"Despite the non-significant efficacy data in the CAPRIE trial for stroke patients, company sales pamphlets (citing CAPRIE) claimed that there was 'proven efficacy' of Plavix over aspirin in ischemic stroke patients." Dickson 4AC ¶170.

New Mexico Complaint	***Dickson* Fourth Am. Compl. ("Dickson 4AC")**
medications." New Mexico Compl. ¶ 50.	"BMS/Sanofi also encouraged physicians to switch patients from aspirin to Plavix if they suffered a stroke while taking aspirin." *Id.* ¶ 172.
"[S]ince March 1998, Defendants have ***falsely and misleadingly promoted Plavix and the CAPRIE trial results by not fully disclosing the results of the trial's subgroups***, and by minimizing and failing to provide all of the data concerning adverse events occurring in the CAPRIE trial and other clinical trials involving Plavix." New Mexico Compl. ¶ 51 (emphasis added).	"***On pamphlets provided to physicians summarizing the CAPRIE study, the subgroup analysis was not provided***. Only the overall 8.7% reduction in the primary endpoint was provided." Dickson 4AC ¶ 169 (emphasis added). "[Although] 'the CAPRIE trial does not provide substantial evidence to support the implication that Plavix has superiority over aspirin,' . . . Defendants nevertheless continue to promote that Plavix is superior to aspirin . . . ." Id. ¶ 12.
"[S]ince March 1998, Defendants have also ***falsely and misleadingly promoted Plavix as being more effective and safer than other competitors, such as Aggrenox***	"[Defendants instructed their employee] to present the data from yet another study in a manner designed ***to confuse physicians and make them believe that Aggrenox***

New Mexico Complaint	***Dickson* Fourth Am. Compl. ("Dickson 4AC")**
Defendants made false and misleading statements about clinical trials involving those competitors when the trial results did not support Defendants' marketing messages." New Mexico Compl. ¶ 53 (emphasis added).	. . . was inferior to Plavix [and] to state that 'it should not be concluded from the study that Aggrenox has similar efficacy and safety to Plavix in stroke patients.'" Dickson 4AC ¶ 20 (emphasis added).
"Defendants falsely and misleadingly promoted Plavix at much higher dosages than those approved by the FDA in order to compensate for the drug's low efficacy, while failing to disclose that Plavix is associated with hemorrhagic adverse events at its recommended dosage and that higher dosages of Plavix increase the risk of those and other adverse events associated with Plavix." New Mexico Compl. ¶ 154.	"On November 23, 1998, FDA's Division of Drug Marketing and Communications ("DDMAC") sent a letter . . . to Defendant Sanofi concerning letters Defendant sent to physicians regarding the use of 300 mg of Plavix as a 'loading dose' immediately prior to coronary stent placement." Dickson 4AC ¶ 14. "[T]he recommended dose of Plavix was 75 mg per day. The use of 300 mg of Plavix as a 'loading dose' for coronary stent placement patients was neither proven to be safe or efficacious nor supported by substantial clinical evidence." *Id.* ¶ 5.

New Mexico Complaint	***Dickson* Fourth Am. Compl. ("Dickson 4AC")**
"[S]ince March 1998, Defendants have also increased Plavix's sales and market share by falsely and misleadingly promoting the drug as being effective and safe for uses for which it had not been demonstrated to be effective or safe." New Mexico Compl. ¶ 55; see also *id.* ¶ 5. "The 2010 ASA Guidelines . . . stated that 'there have been no clinical trials to indicate that switching antiplatelet agents reduces the risk for subsequent events.' . . . Defendants knew or should have known that switching patients from another antiplatelet medication to Plavix had not been shown to reduce the risk for subsequent events, yet Defendants have falsely, deceptively, and unfairly misrepresented and promoted such medication changes at all relevant times . . . ." *Id.* ¶ 56.	"BMS/Sanofi also encouraged physicians to switch patients from aspirin to Plavix if they suffered a stroke while taking aspirin. According to ASA, however, 'there have been no clinical trials to indicate that switching antiplatelet agents reduces the risk for subsequent events.'" Dickson 4AC ¶ 172.

C. Section I.C. of the factual allegations section of the State's Complaint: **"Additional False, Deceptive, and Unfair Conduct Concerning Important Safety Information."** New Mexico Compl. ¶¶ 61-68.

New Mexico Complaint	***Dickson* Fourth Am. Compl. ("Dickson 4AC")**
"[T]he CAPRIE trial results showed less gastrointestinal bleeding in patients taking Plavix than in patients taking aspirin. But, the dosage of aspirin used in the trial—325 mg daily—is more than four times higher than the average dosage physicians advise for their patients." New Mexico Compl. ¶ 61.	"The CAPRIE trial also showed that there was less gastrointestinal bleeding in patients taking Plavix compared to aspirin. However, the aspirin dose used in CAPRIE was 325 mg per day for all patients. Presently, physicians recommend an aspirin dose of as little as 50 mg per day…. Dickson 4AC ¶ 174.
"Defendants knew or should have known of the misleading nature of the CAPRIE trial results since at least March 1998, yet Defendants falsely and misleadingly marketed Plavix as being as safe or safer than aspirin based on the CAPRIE trial results." New Mexico Compl. ¶ 61.	"BMS/Sanofi ordered its sales force to promote Plavix as comparably safe to aspirin based on the CAPRIE study even though the CAPRIE study compared Plavix to a more toxic dose of aspirin that is not regularly prescribed today." Dickson 4AC ¶ 174.

New Mexico Complaint	***Dickson* Fourth Am. Compl. ("Dickson 4AC")**
"Defendants have never compared Plavix to a lower dosage of aspirin in a clinical trial." New Mexico Compl. ¶ 62.	"BMS/Sanofi have not further tested Plavix against aspirin to determine whether a more commonly prescribed (i.e., lower) dose of aspirin supports BMS/Sanofi's claims that Plavix imposes a lower risk of gastrointestinal bleeding when compared to aspirin (as its used in a therapeutic context)." Dickson 4AC ¶ 175.
"[I]n [the "Chan Study"] … Plavix was demonstrated to cause appreciably more gastrointestinal bleeding than aspirin taken in conjunction with Prilosec … in patients with a history of aspirin-induced ulcers. The study demonstrated that switching patients who had aspirin-induced ulcers from aspirin to Plavix is neither safe nor anywhere near as cost-effective as adding Prilosec to aspirin therapy." New Mexico Compl. ¶ 62.	"[I]n [the "Chan Study"] Plavix was shown to cause significantly more gastrointestinal bleeding than aspirin plus . . . Prilosec[ ] in patients with a history of aspirin-induced ulcers. The Chan Study showed that switching patients to Plavix if they have ulcers with aspirin is not safe and that it would be cheaper to simply add esomeprazole (an inexpensive over-the-counter medication) to aspirin." Dickson 4AC ¶ 175.

New Mexico Complaint	***Dickson* Fourth Am. Compl. ("Dickson 4AC")**
"Defendants . . . did not disclose the results of [the Chan] study to healthcare professionals or the general public…." New Mexico Compl. ¶ 62.	"The results of the Chan Study were not disclosed to prescribing neurologists." Dickson 4AC ¶ 175.

D. Section I.D. of the factual allegations section of the State's Complaint: **"Defendants' False and Misleading Representations and Omissions Regarding the Alleged Effectiveness, Safety and Superiority of Plavix Caused Third Parties to Submit Claims for Reimbursement to the State of New Mexico That Were False Within the Meaning of New Mexico Law."** New Mexico Compl. ¶¶ 69-74.

New Mexico Complaint	***Dickson* Fourth Am. Compl. ("Dickson 4AC")**
"Defendants, in marketing Plavix, knew that pharmacies and other facilities supplying Plavix to patients throughout New Mexico would routinely be seeking reimbursement from the State of New Mexico under its Medicaid (and related) programs." New Mexico Compl. ¶ 69.	"BMS/Sanofi knowingly participated in a comprehensive scheme to defraud the New Mexico government while illegally and deceptively promoting Plavix to further increase Plavix sales within the State of New Mexico." Dickson 4AC ¶ 339.

New Mexico Complaint	***Dickson* Fourth Am. Compl. ("Dickson 4AC")**
"Defendants, in marketing Plavix, knew that pharmacies and other facilities supplying Plavix to patients throughout New Mexico would routinely be seeking reimbursement from the State of New Mexico under its Medicaid (and related) programs. As a result, Defendants, by promoting Plavix as safer and more effective than other medications when it was not, at 100 times the cost of available alternatives, ***knowingly caused innocent third parties to submit claims for reimbursement to the State of New Mexico that Defendants knew or should have known did not qualify for payment."*** New Mexico Compl. ¶ 69 (emphasis added)	"BMS/Sanofi's actions ***knowingly caused physicians and pharmacists in New Mexico to impliedly make false certifications about Plavix's cost effectiveness (and medical necessity)*** for the patient's treatment. Specifically, a prescription written for Plavix was a certification that the Plavix met the requirements for Medicaid coverage in New Mexico." Dickson 4AC ¶ 341 (emphasis added).
"By [causing the submission of false reimbursement claims]. Defendants obtained, by means of false or fraudulent	"By virtue of the above-described acts, Defendants knowingly made, used, or caused to be made or used false

New Mexico Complaint	***Dickson* Fourth Am. Compl. ("Dickson 4AC")**
representation or promise, large sums of money from the State of New Mexico in connection with delivery of or payment for health care benefits . . . paid for or reimbursed or subsidized by the state." New Mexico Compl. ¶ 70.	records and statements, and omitted material facts, to induce the New Mexico State Government to approve and pay such false and fraudulent claims." Dickson 4AC ¶ 340.
"Defendants' misleading conduct, statements and omissions regarding the alleged effectiveness, superiority, and safety of Plavix deprived . . . the State of New Mexico of the ability to accurately determine whether the drug was in fact 'medically necessary' in any given situation." New Mexico Compl. ¶ 72.	"BMS/Sanofi fraudulently induced New Mexico's state review board to place Plavix on New Mexico's formulary for indications for which Plavix has no therapeutic advantage over aspirin and is 100 times more expensive. Thus, BMS/Sanofi knowingly caused New Mexico to . . . to pay for Plavix when Plavix was prescribed for . . . indications [that] did not meet formulary requirements." Dickson 4AC ¶ 342.
"By writing prescriptions for Plavix for which reimbursement would be sought through public assistance programs, ***physicians were certifying by***	"BMS/Sanofi[ ] . . . knowingly caused physicians and pharmacists in New Mexico to ***impliedly make false certifications about Plavix's cost***

New Mexico Complaint	***Dickson* Fourth Am. Compl. ("Dickson 4AC")**
implication that the treatment was safe, medically necessary and cost-effective, when in fact it was not . . . ." New Mexico Compl. ¶ 73 (emphasis added).	***effectiveness (and medical necessity) for the patient's treatment***. Specifically, a prescription written for Plavix was a certification that the Plavix met the requirements for Medicaid coverage." Dickson 4AC ¶ 341 (emphasis added).
"[B]y causing physicians to unwittingly certify that Plavix was medically necessary and cost-effective when it was not, ***Defendants knowingly caused the submission of a false claims to the State of New Mexico in violation of New Mexico law***." New Mexico Comp. ¶ 74 (emphasis added).	"BMS/Sanofi's misrepresentations . . . caused physicians to prescribe Plavix in New Mexico when Plavix did not in fact meet requirements for New Mexico's Medicaid coverage because a cheaper alternative existed that was at least just as effective. As a result, ***BMS/Sanofi knowingly caused the submission of false claims for payment by New Mexico in violation of the New Mexico Medicaid False Claims Act***." Dickson 4AC ¶ 341 (emphasis added).

E. Section I.E. of the factual allegations section of the State's Complaint: **"The FDA's Repeated Objections to Defendants' False, Deceptive, and Unfair Marketing."** New Mexico Compl., ¶¶ 75-80.

New Mexico Complaint	***Dickson* Fourth Am. Compl. ("Dickson 4AC")**
"[O]n November 23, 1998, [DDMAC] reprimanded Sanofi, stating that Defendants' dissemination of a letter [was unlawful] because it promoted Plavix for an unapproved use (immediately prior to coronary artery stent placement) . . . . "New Mexico Compl. ¶ 76.	"On November 23, 1998, [DDMAC] sent a letter to Defendant Sanofi concerning letters Defendant sent to physicians regarding the use of 300 mg of Plavix as a 'loading dose' immediately prior to coronary stent placement." Dickson 4AC ¶ 4.
"On May 9, 2001, DDMAC alerted Sanofi that its dissemination of a particular visual aid for Plavix contained false or misleading promotional claims because it overstated the drug's efficacy, included an unsubstantiated superiority claim about Plavix relative to aspirin, and included a misleading efficacy presentation." New Mexico Compl. ¶ 78.	"On May 9, 2001, DDMAC sent another letter to Defendant Sanofi objecting to its promotional efforts for Plavix . . . ." Dickson 4AC, ¶ 8. "Specifically, DDMAC found that the sales aid overstated the efficacy of Plavix, made unsubstantiated superiority claims, constituted a misleading efficacy presentation and lacked fair balance." *Id.* ¶ 10.

New Mexico Complaint	***Dickson* Fourth Am. Compl. ("Dickson 4AC")**
"On March 26, 2009, DDMAC again reprimanded Sanofi, stating that three of its internet advertisements were misleading because they made representations or suggestions about the efficacy of Plavix but failed to communicate any risk information associated with the use of the drug, thereby indicating that Plavix is safer than has been demonstrated." New Mexico Compl. ¶ 80.	"On March 26, 2009, DDMAC sent another letter to Defendant Sanofi after determining that Plavix internet advertisements misbranded Plavix . . . ." Dickson 4AC, ¶ 13. "DDMAC concluded that Sanofi failed to provide any risk information and stated in relevant part: '. . . By omitting the most serious and frequently occurring risks associated with PLAVIX, the sponsored links misleadingly suggest that PLAVIX is safer than has been demonstrated.'" *Id*. ¶ 14.

F. Section I.F. of the factual allegations section of the State's Complaint: **"The Impact of Defendants' False, Deceptive, and Unfair Marketing of Plavix."** New Mexico Compl., ¶¶ 81-95.

New Mexico Complaint	***Dickson* Fourth Am. Compl. ("Dickson 4AC")**
"Defendants launched and maintained a massive promotional campaign to increase Plavix's sales and market share." New	"BMS/Sanofi knowingly participated in a comprehensive scheme to defraud the New Mexico government while

New Mexico Complaint	***Dickson* Fourth Am. Compl. ("Dickson 4AC")**
Mexico Compl. ¶ 81. "Defendants engaged in a premeditated program to influence consumers, prescribers, and the State of New Mexico to believe that Plavix was a superior drug when it was not." *Id.* ¶ 90.	illegally and deceptively promoting Plavix to further increase Plavix sales within the State of New Mexico." Dickson 4AC ¶ 339.
"Relying upon Defendants; promises of superior treatment and better outcomes compared with aspirin and other competitor drugs, the State of New Mexico paid a hefty premium for a drug that in truth was no more efficacious than far cheaper drugs, but was far more dangerous." New Mexico Compl. ¶ 91. "Defendants' false, misleading, and deceptive marketing of Plavix resulted in millions of dollars of Plavix ***sales to the State of New Mexico . . . that otherwise would not have been made***." *Id.* ¶ 93 (emphasis added); *see also id.* ¶ 146 ("As a result of Defendants' fraudulent	"[U]naware of the falsity of the records, statements and claims made . . . or caused to be made . . . by Defendants, ***[the State of New Mexico] paid and continues to pay the claims that would not be paid but for Defendants' illegal inducements and/or business practices***." Dickson 4AC ¶ 343 (emphasis added).

New Mexico Complaint	***Dickson* Fourth Am. Compl. ("Dickson 4AC")**
marketing of Plavix, the State of New Mexico has paid millions of dollars for Plavix and has paid excessive prices for Plavix.")	

APPENDIX K

*** * FOR PUBLICATION * ***

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

In re PLAVIX MARKETING, SALES PRACTICE AND PRODUCTS LIABILITY LITIGATION (NO. II)	MDL DOCKET NO. 2418
UNITED STATES OF AMERICA, *et al.*, ex rel. ELISA DICKSON, Plaintiffs, v. BRISTOL-MYERS SQUIBB CO., *et al*, Defendants.	Civil Action No. 13-1039 (FLW) (LHG) **OPINION**

WOLFSON, United States District Judge:

Before the Court is the motion of Defendants Bristol-Myers Squibb Company ("BMS"), Sanofi-Aventis U.S. LLC, Sanofi U.S. Service Inc., and Sanofi-Synthelabo Inc. (collectively "Sanofi") (together with BMS, "Defendants") to dismiss the Fourth Amended Complaint ("4AC") of relator Elisa Dickson ("Realtor"). In the 4AC, Relator brings a qui tam action, a member case of the Multi-District Litigation, In re: Plavix Marketing, Sales Practices and Products Liability Litigation, involving the alleged wrongful marketing and sales of Plavix (clopidogrel

bisulfate), a prescription blood thinner manufactured by Defendant BMS and marketed in the United States by BMS and Sanofi. Relator brings this case on behalf of the United States and seventeen states, asserting claims for violation of the federal False Claims Act ("FCA"), 31 U.S.C. §§ 3729–3733 (Count I); conspiracy under the FCA, 31 U.S.C. § 3729(a) (Count II); and the False Claims Acts of twenty-four (24) states (Counts III-XXVI). Defendants move to dismiss the 4AC in its entirety, and in the alternative to limit the temporal scope of Relator's state FCA claims under the laws of five states, the FCAs of which became effective after March 30, 2005.

For the reasons stated herein, the Defendants' Motion to Dismiss the 4AC is GRANTED, and Defendants' motion to restrict the retroactive application of the five state FCAs, which became effective after March 30, 2005, is denied as moot.

I. FACTUAL BACKGROUND

The relevant facts of this action, as set forth in the 4AC and taken as true by this Court, are as follows. Plavix® (clopidogrel bisulfate) ("Plavix") is a prescription blood thinner manufactured by BMS and comarketed in the United States by Sanofi. 4AC ¶ 1. Plavix has been approved by the United States Food and Drug Administration ("FDA") and is indicated for the treatment of Acute Coronary Syndrome and for use following a recent myocardial infarction or stroke or established peripheral artery disease. *Ibid.* Plavix costs approximately $4.00 per pill. Aspirin, an over-the-counter blood thinner, costs approximately $0.04 per pill. *Id.* at ¶ 3.

Relator claims that Defendants promoted Plavix as a superior drug to aspirin for certain indicated usages, when Plavix was no more effective than aspirin for those indicated usages and cost one hundred times more. *Id.* at ¶ 22. More than half of state Medicaid programs contain

cost-based restrictions that limit coverage under Medicaid to cost-effective treatments. *Ibid.* In these states, Medicaid only pays for cost-effective drugs. *Ibid.* Where an equally effective but cheaper treatment is available for a particular course of treatment, the more expensive drug is not cost effective and cannot be reimbursed. *Ibid.* In these states, cost effectiveness is not just a requirement for participation in Medicaid, it is a condition precedent to reimbursement designed to ensure that a state's Medicaid program is a good steward of taxpayer dollars. *Ibid.*

Relator alleges that Defendants targeted their marketing efforts, misrepresenting the effectiveness of Plavix relative to aspirin, at physicians and prescribers whose patients relied upon public assistance programs such as Medicaid. *Id.* at ¶ 3. Relator claims that Defendants' marketing efforts caused physicians to submit many prescriptions for Plavix in the mistaken belief that it was a cost-effective treatment. *Ibid.*

In order for the cost of a drug to be reimbursed under Medicaid, the drug manufacturer must have entered into, and have in effect, a rebate agreement wherein the manufacturer agrees to give the applicable government payor back a percentage of the cost of the reimbursed drug. *Id.* at ¶ 92. Drugs that are covered by a rebate agreement are then statutorily divided into two distinct categories: those that require prior authorization from Medicaid prior to reimbursement and those that are reimbursed automatically when the drug is prescribed. *Ibid.* Each state maintains a preferred drug list, or formulary[1], that explicitly

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[1] The 4AC Complaint defines the term "preferred drug list" as equivalent to or interchangeable with the term "formulary." *Id.* at ¶ 92. Defendants correctly object in their motion papers that these terms have distinct legal meanings. "Formularies" are described under 42 U.S.C. § 1396r- 8(d)(4), while "preferred drug lists" ("PDL"), exempting drugs from "prior authorization programs," are described under § 1396r-8(d)(5). However, as it is clear from the 4AC that

exempts certain Medicaid-eligible drugs from a prior authorization requirement. Medicaid is obligated to provide reimbursement for the cost of a drug on a state's formulary when the drug is prescribed by a physician for an "on-label" indication. *Ibid.* In other words, if a drug is on a state's formulary, once an "on-label" prescription for that drug is written and the prescription is filled, the cost for that prescribed drug is automatically reimbursed by the government. No other authorizations are required. *Id.* at ¶ 26.

In addition to marketing to prescribing physicians, Relator also alleges that Defendants falsely marketed Plavix to the physicians and pharmacists on state formulary committees as a cost effective treatment eligible for listing on the states' formularies, when Plavix was not in fact so eligible, due to its lack of superior effectiveness to aspirin and significantly greater cost. *Id.* at ¶ 151. Relator claims that these marketing efforts fraudulently induced the formulary committees to include Plavix on each state's PDL/formulary, which triggered an automatic government obligation to reimburse Plavix prescriptions—even when Plavix did not meet the cost-effectiveness requirements for inclusion on the formulary. *Ibid.* Relator alleges that reimbursements for Plavix in this context constitute false claims under the FCA and under the state FCAs. *Ibid.*

II. PROCEDURAL HISTORY

On March 30, 2011, Relator filed this case in the United States District Court for the Southern District of Illinois ("the transferor court"). The United States and its

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Relator is concerned with the placement of Plavix on PDLs only, and merely also refers to these lists as formularies, the legal distinction between these terms as used in the Medicaid statute does not affect the Court's decision. *See* 4AC ¶¶ 25, 100.

co-plaintiff States declined to intervene in Relator's claims. On November 29, 2012, Relator filed a Second Amended Complaint. Defendants moved to dismiss that pleading, and the transferor court granted that motion in part and denied it in part ("*Dickson* I"). See 289 F.R.D. 271 (S.D. Ill. 2013) (Dkt. No. 54.).

The Judicial Panel on Multidistrict Litigation then transferred the case to this Court to be part of the Plavix® Multi-District Litigation. This Court then vacated *Dickson* I, in part, upon reconsideration, granted further dismissal in part, and granted Relator leave to amend her pleading ("*Dickson* II"). *See* 2013 WL 7196328 (D.N.J. Aug. 21, 2013) (Dkt. No. 88). On September 20, 2013, Relator filed a 149-page Third Amended Complaint ("3AC"). The 3AC's Prescriber Allegations and Formulary Allegations asserted that Defendants violated the federal FCA and numerous state FCAs by causing the submission of false claims for Medicare and Medicaid payment. Defendants moved to dismiss the 3AC in its entirety. On August 20, 2015, the Court granted Defendants' motion in part and denied it in part. The Court dismissed (1) all FCA claims based on Medicare Part D; (2) federal FCA claims based on the Medicaid plans of thirty-three (33) states, including the District of Columbia; (3) all FCA claims based on Plavix's inclusion on state formularies; (4) state FCA claims raised under the law of nineteen (19) states; and (5) all federal and state FCA claims for claims made prior to March 30, 2005, pursuant to the applicable statutes of limitations. *See Dickson* III, 123 F. Supp. 3d at 619.

The active claims remaining in the case after the Court's decision were (1) federal FCA claims based on Defendants' conduct in 17 States—Connecticut, Delaware, Idaho, Kansas, Maryland, Massachusetts, Mississippi, Montana, Nebraska, North Carolina, Ohio, Oklahoma, Rhode Island, South Dakota, Utah, Washington and

Wyoming—each of which imposes a cost-effectiveness requirement as a condition for the reimbursement of drugs under that state's Medicaid program ("the Cost-Imposed States"); and (2) state FCA claims under the law of the seven Cost-Imposed States that have enacted their own FCAs — Connecticut, Delaware, Massachusetts, Montana, North Carolina, Oklahoma, and Rhode Island.

On December 15, 2015, the Court stayed this case pending the Supreme Court's decision in *Universal Health Servs., Inc. v. United States and Massachusetts, ex rel. Escobar*, —— U.S. ——, 136 S. Ct. 1989, 2001, 195 L. Ed. 2d 348 (2016)) (hereinafter "*Escobar*"). On June 16, 2016, the Supreme Court decided *Escobar*. These proceedings were reopened on June 29, 2016.

On August 16, 2016, without seeking leave to amend, Relator filed her fifth pleading: the 175-page Fourth Amended Complaint ("4AC"). The 4AC asserts claims for violation of the federal FCA, 31 U.S.C. §§ 3729-3733 (Count I), and for conspiracy to violate the federal FCA, 31 U.S.C. § 3729(a) (Count II), based on allegedly false Medicaid claims submitted in thirty-six (36) states. In addition to federal FCA claims based on conduct in the 17 Cost-Imposed States that this Court previously allowed to go forward, Relator also includes claims in 19 states – Alabama, Alaska, Arizona, Arkansas, Colorado, Florida, Georgia, Hawaii, Iowa, Louisiana, Maine, Michigan, Minnesota, Nevada, New Jersey, New Mexico, Oregon, Tennessee, Wisconsin which this Court previously dismissed. Relator claims that these states too impose cost-effectiveness requirements in their Medicaid reimbursement schema, which were simply not pleaded in the 3AC. The 4AC also asserts claims under 24 state FCAs.[2] This figure

[2] *See* California FCA (Cal. Gov. Code §§ 12650-12655) (Count III); Colorado Medical FCA (C.R.S. § 25.5-4-304 *et seq.*) (Count IV); Connecticut False Claims Act (CONN. GEN. STAT. ANN. § 17b-301a et seq.) (Count V); Delaware False Claims and Reporting Act (6 DEL.

includes 17 state FCA claims, which this Court previously dismissed — California, Colorado, Florida, Georgia, Illinois, Indiana, Michigan, Minnesota, Nevada, New Jersey, New Mexico, New York, Tennessee, Texas, Virginia, Wisconsin, District of Columbia. Again, Relator's rationale for resurrecting these claims is that these states also impose cost-effectiveness requirements, which were previously not pleaded. Relator's federal and state FCA claims in the 4AC incorporate this Court's previous ruling on the statutes of limitations, and do not seek recovery for false claims arising prior to March 30, 2005, except for revived previously dismissed claims under four State FCAs with

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CODE ANN. § 1201(a)(1) and (2)) (Count VI); Florida False Claims Act (FL. STAT. §§ 68.081- 68.090) (Count VII); Georgia False Medicaid Claims Act (GA. CODE 49-4-168 et seq.) (Count VIII); Illinois Whistleblower Reward and Protection Act (740 ILCS 175, et seq.) (Count IX); Indiana State False Claims and Whistleblowers Protection Act (IND. CODE ANN. § 5-11-5.5-1 - 5-11-5.5-18) (Count X); Massachusetts False Claims Act (MASS. GEN. LAWS c.12 § 5(A)) (Count XI); Michigan Medicaid False Claims Act (Mich. Comp. Laws §§ 400.601-400.613) (Count XII); Minnesota False Claims Act (MINN. STAT. § 15.C01 et. seq) (Count XIII); Montana False Claims Act (MONT. CODE ANN. §§ 17-8-401 – 17- 8-412) (Count XIV); Nevada False Claims Act (NEV. REV. STAT. ANN. §§ 357.01-.250) (Count XV); New Jersey False Claims Act (N.J. STAT. § 2A:32C-1-17) (Count XVI); New Mexico Medicaid False Claims Act (N.M. STAT. ANN. § 27-14-1- - 27-14-15) (Count XVII); New York False Claims Act (N.Y. St. Finance Law § 187 et seq.) (Count XVIII); North Carolina False Claims Act (N.C. GEN. STAT. § 1-605 – 618, § 108A-63) (Count XIX); Oklahoma False Claims Act (63 OKLA. STAT. §§ 5053-5053.7) (Count XX); Rhode Island's State False Claims Act (R.I. GEN. LAWS §§ 9-1.1-1 – 9-1.1-8) (Count XXI); Tennessee Medicaid False Claims Act (TENN. CODE. ANN. §§ 71-5-181 to -185) (Count XXII); Texas Medicaid Fraud Prevention Act (TEX. HUM. RES. CODE ANN 36.001-.132) (Count XXIII); Virginia Fraud Against Taxpayers Act (VA CODE ANN. 8.01-2.16. 1-216.19) (Count XXIV); Wisconsin State Law Claims for Violations of the Wisconsin False Claims Act (WIS. STAT. § 20.931) (Count XXV); District of Columbia Procurement Reform Amendment Act (D.C. CODE ANN. §§ 2-308.13-.15) (Count XXVI).

longer or shorter limitations periods: New Mexico (four years), New York (10 years), Texas (four years), and Wisconsin (10 years). 4AC ¶ 51 n. 54.

On January 30, 2017, Defendants moved to dismiss the 4AC in its entirety. On May 1, 2017, the Third Circuit issued its first reported opinion interpreting the Supreme Court's decision in *Escobar*. Defendants submitted a notice of supplementary authority on May 8, 2017, contending that the Third Circuit's precedential decision in *United States ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481 (3d Cir. 2017), compelled the dismissal of the 4AC for failure to allege that Defendants' fraud was material to any government Medicaid payor's decision to pay for Plavix. Relator opposed Defendants' arguments concerning *Petratos* on May 11, 2017.

III. LEGAL STANDARD

This Court has federal-question jurisdiction over the federal FCA claims under 28 U.S.C. § 1331 and 31 U.S.C. § 3732(a). Supplemental jurisdiction extends to the state FCA claims under 28 U.S.C. § 1367. *See also United States ex rel. Wilkins v. United Health Grp., Inc.,* 659 F.3d 295, 302 (3d Cir. 2011). "The law of the transferee forum applies . . . to federal questions, though the Court may give the law of the transferor forum 'close consideration.'" *In re Nazi Era Cases Against German Defendants Litig.*, 320 F. Supp. 2d 204, 214 (D.N.J. 2004), *aff'd*, 153 F. App'x 819 (3d Cir. 2005) (citing *In re Korean Air Lines Disaster,* 829 F.2d 1171 (D.C.Cir. 1987)). Accordingly, in considering the present motion to dismiss, the precedents of the Third Circuit control the merits of Relator's federal FCA claims. *In re Nazi Era Cases Against German Defendants Litig.*, 198 F.R.D. 429, 439 n.16 (D.N.J. 2000) ("When dealing with cases that have been consolidated for pretrial proceedings pursuant to an order of the MDL Panel under 28 U.S.C. § 1407, the law of the transferor forum merits close attention, but should not be read to

have stare decisis effect in a transferee forum situated in another circuit. *See In re Korean Air Lines Disaster*, 829 F.2d 1171, 1176 (D.C. Cir. 1987). For this reason the Court will apply the law of the Third Circuit, with due consideration given to the rulings of other circuits.").[3] Because the Court exercises supplemental jurisdiction over the state FCA claims under the laws of twenty-four states, the Court must apply the state substantive law of each respective state to that state's FCA claim. *Silverstein v. Percudani*, 422 F. Supp. 2d 468, 471 (M.D. Pa.), *aff'd*, 207 F. App'x 238 (3d Cir. 2006) ("A federal district court

[3] *See also In re Donald J. Trump Casino Sec. Litig.-Taj Mahal Litig.*, 7 F.3d 357, 368 n. 8 (3d Cir. 1993) (assuming without deciding that the district court was correct that in multidistrict transfers, the precedent of the Third Circuit as the transferee court controls on issues of federal law, while the circuit precedent of the transferor court merits close consideration); *In re Managerial, Prof'l & Tech. Employees*, No. 02-CV-2924, 2006 WL 38937, at *2 (D.N.J. Jan. 5, 2006) (quoting *Korean Air Lines*, 829 F.2d at 1174 (quoting Marcus, *Conflict Among Circuits and Transfers Within the Federal Judicial System*, 93 Yale L.J. 677, 721 (1984))) ("Where the claim arises under federal law, as is the case here, the appropriate course is to apply the law of the transferee court. In considering the issue, the D.C. Circuit Court of Appeals recognized that the pretrial nature of multidistrict transfers suggests that the law of the origin circuit should apply, while the presumed uniformity of federal law across circuits suggests that doing so would be unnecessary. After considering these competing views, the court decided that "the transferee court [should] be free to decide a federal claim in the manner it views as correct without deferring to the interpretation of the transferor circuit.""); *In re National Century Financial Enterprises, Inc., Inv. Litigation*, 323 F. Supp. 2d 861, 876 (S.D. Ohio 2004) ("the rule in multidistrict litigation is that the transferee court, in interpreting federal law, should apply the law of its own circuit rather than the law of the transferor court's circuit."); *In re StarLink Corn Prod. Liab. Litig.*, 211 F. Supp. 2d 1060, 1063 (N.D. Ill. 2002) (applying *Korean Air Lines* and *McMasters v. United States*, 260 F.3d 814, 819 (7th Cir. 2001) to find that, on questions of federal law, circuit precedent from the transferee court applies unless the federal law is specifically intended to be geographically non-uniform).

exercising supplemental jurisdiction over state law causes of action must apply the substantive law of the State [providing the cause of action] as interpreted by the State's highest court.").

When considering a motion to dismiss a complaint for failure to state a claim upon which relief can be granted, pursuant to Fed. R. Civ. P. 12(b)(6), a court must accept all well-pleaded allegations in the complaint as true and view them in the light most favorable to the plaintiff. *Evancho v. Fisher,* 423 F.3d 347, 351 (3d Cir. 2005). It is well settled that a pleading is sufficient if it contains "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). However, "[a]lthough the Federal Rules of Civil Procedure do not require a claimant to set forth an intricately detailed description of the asserted basis for relief, they do require that the pleadings give defendant fair notice of what the plaintiff's claim is and the grounds upon which it rests." *Baldwin Cnty. Welcome Ctr. v. Brown,* 466 U.S. 147, 149–50 n. 3 (1984) (quotation and citation omitted). A district court, in weighing a motion to dismiss, asks "'not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claim.'" *Bell Atlantic v. Twombly,* 550 U.S. 544, 583 (2007) (quoting *Scheuer v. Rhodes,* 416 U.S. 232, 236 (1974)); *see also Ashcroft v. Iqbal,* 556 U.S. 662, 684 (2009) ("Our decision in *Twombly* expounded the pleading standard for all civil actions.") (internal citations omitted); *Fowler v. UPMC Shadyside,* 578 F.3d 203, 210 (3d Cir. 2009) ("*Iqbal* ... provides the final nail-in-the-coffin for the 'no set of facts' standard that applied to federal complaints before *Twombly*.").

Following the *Twombly/Iqbal* standard, the Third Circuit applies a two-part analysis in reviewing a complaint under Rule 12(b)(6). First, a district court must accept all of the complaint's well-pleaded facts as true, but

may disregard any legal conclusions. *Fowler,* 578 F.3d at 210. Second, a district court must determine whether the facts alleged in the complaint are sufficient to show that the plaintiff has a "plausible claim for relief." *Id.* A complaint must do more than allege the plaintiff's entitlement to relief. *Id.* However, this standard "'does not impose a probability requirement at the pleading stage,' but instead 'simply calls for enough facts to raise a reasonable expectation that discovery will reveal evidence of' the necessary element.'" *Phillips v. Cnty. of Allegheny,* 515 F.3d 224, 234 (3d Cir. 2008) (quoting *Twombly,* 127 S. Ct. at 1965); *see also Covington v. Int'l Ass'n of Approved Basketball Officials,* 710 F.3d 114, 118 (3d Cir. 2013) ("[A] claimant does not have to set out in detail the facts upon which he bases his claim. . . . The pleading standard is not akin to a probability requirement, . . . to survive a motion to dismiss, a complaint merely has to state a plausible claim for relief." (citations omitted)). Nonetheless, a court need not credit either "bald assertions" or "legal conclusions" in a complaint when deciding a motion to dismiss. *In re Burlington Coat Factory Sec. Litig.,* 114 F.3d 1410, 1429–30 (3d Cir. 1997). The defendant bears the burden of showing that no claim has been presented. *Hedges v. U.S.,* 404 F.3d 744, 750 (3d Cir. 2005) (citing *Kehr Packages, Inc. v. Fidelcor, Inc.,* 926 F.2d 1406, 1409 (3d Cir. 1991)).

Finally, a court in reviewing a Rule 12(b)(6) motion must only consider the facts alleged in the pleadings, the documents attached thereto as exhibits, and matters of judicial notice. *Southern Cross Overseas Agencies, Inc. v. Kwong Shipping Grp. Ltd.,* 181 F.3d 410, 426 (3d Cir. 1999).

Because FCA claims allege fraud, they are subject to the heightened pleading requirements of Federal Rule of Civil Procedure 9(b). *Wilkins*, 659 F.3d at 301 n. 9; *Frederico v. Home Depot*, 507 F.3d 188, 202–03 (3d Cir. 2007). In order to satisfy Rule 9(b), a complaint must

provide "all of the essential factual background that would accompany 'the first paragraph of any newspaper story'—that is, the 'who, what, when, where and how' of the events at issue." *In re Rockefeller Ctr. Props., Inc. Sec. Litig.*, 311 F.3d 198, 217 (3d Cir. 2002) (quoting *Burlington Coat Factory*, 114 F.3d at 1422). In order to satisfy the standards of 9(b) in the FCA context Relator "must provide particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted. Describing a mere opportunity for fraud will not suffice. Sufficient facts to establish a plausible ground for relief must be alleged." *Foglia v. Renal Ventures Mgmt., LLC*, 754 F.3d 153, 157–58 (3d Cir. 2014) (quotations omitted). *See also id.* at 156 (In *United States ex Rel. Wilkins* . . ., we noted that we had never "held that a plaintiff must identify a specific claim for payment *at the pleading stage* of the case to state a claim for relief.").

IV. ANALYSIS

"[T]he FCA makes it unlawful to knowingly submit a fraudulent claim to the government."[4] *U.S. ex rel. Schumann v. Astrazeneca Pharm. L.P.*, 769 F.3d 837, 840 (3d Cir. 2014). "The primary purpose of the FCA is to indemnify the government-through its restitutionary penalty provisions-against losses caused by a defendant's fraud." *Wilkins*, 659 F.3d at 304 (quotation omitted). To that end, the Act contains a *qui tam* provision that permits private

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[4] The FCA as FERA has amended it, now imposes liability on:

[A]ny person who—

(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim[.]

31 U.S.C. § 3729(a)(1); *Wilkins*, 659 F.3d at 303.

parties (known as "relators") to bring suit "on behalf of the United States against anyone submitting a false claim to the Government." *Schumann*, 769 F.3d at 840 (internal quotation marks omitted) (quoting *Hughes Aircraft Co. v. U.S. ex rel. Schumer*, 520 U.S. 939, 941 (1997)). If a *qui tam* suit is successful, the relator has the opportunity to share in the recovery.

The Third Circuit has recognized that "[t]here are two categories of false claims" that may form the basis of an FCA *qui tam* suit: (1) factually false claims; and (2) legally false claims. *Wilkins*, 659 F.3d at 305. "'A claim is factually false when the claimant [knowingly] misrepresents what goods or services that it provided to the Government.' '[A] claim is legally false when the claimant knowingly falsely certifies that it has complied with' a material statute, regulation, or contractual provision. Such certification may be express or implied. 'Under the 'express false certification' theory, [a claimant] is liable under the FCA for falsely certifying that it is in compliance with' a material statute, regulation, or contractual provision." *United States v. Eastwick Coll.*, 657 F. App'x 89, 93–94 (3d Cir. 2016) (quoting *Wilkins*, 659 F.3d at 305). "By contrast, implied false certification liability attaches when a claimant 'makes specific representations about the goods or services provided' and the claimant's 'failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths.'" *Id.* (quoting *Escobar*, 136 S. Ct. at 2001).[5] "[T]he implied certification theory of liability should not be applied expansively, particularly when advanced on the basis of FCA allegations arising from the Government's payment of claims under federally funded

[5] "The FCA defines 'material' as 'having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.'" *Wilkins*, 659 F.3d at 303 (quoting 31 U.S.C. § 3729(b)(4)).

health care programs." *Wilkins*, 659 F.3d at 307. "Thus, under this theory a plaintiff must show that if the Government had been aware of the defendant's violations of the Medicare [or Medicaid] laws and regulations that are the bases of a plaintiff's FCA claims, it would not have paid the defendant's claims." *Ibid.*

In addition to factually false and legally false claims, the federal courts have recognized a narrow, third category of false claims obtained by "fraud-in-the-inducement." "[A] fraudulently induced contract may create liability under the False Claims Act when that contract later results in payment thereunder by the government, whether to the wrongdoer or someone else." *United States v. Veneziale*, 268 F.2d 504, 505 (3d Cir. 1959) (citing *United States ex rel. Marcus v. Hess,* 317 U.S. 537 (1943) (superseded by statute)). *See also U.S. ex rel. Thomas v. Siemens AG*, 593 F. App'x 139, 143 (3d Cir. 2014) ("Although the focus of the False Claims Act is on false 'claims,' courts have employed a fraudulent inducement theory to establish liability under the Act for each claim submitted to the government under a contract which was procured by fraud, even in the absence of evidence that the claims were fraudulent in themselves.").

In the 4AC, Relator pursues her federal and state FCA claims under both implied false certification and fraud-in-the-inducement theories of liability. First, Relator contends that Defendants caused physicians to submit prescriptions to Medicaid for payment by fraudulently marketing Plavix to those physicians as more effective than aspirin, despite Plavix being one- hundred times more expensive and no more effective. Relator contends that the claims to Medicaid, submitted by physicians who were subjected to Defendants' marketing efforts, contained an implied false certification that Plavix complied with state Medicaid program requirements that all prescriptions submitted for payment be for drugs that are

cost-effective treatments. Because Plavix costs one-hundred times more than aspirin, but Relator alleges it to be no more effective, Relator contends that Plavix was not cost-effective and was not eligible for reimbursement under the laws of the thirty-six states imposing cost-effectiveness requirements in their Medicaid program. The Court shall refer to this category of claims as the "Prescriber Allegations."

Second, relying explicitly on the fraud-in-the-inducement theory enunciated by the Third Circuit in the context of a fraudulently induced contract in the unreported decision in *Thomas*, Relator contends that Defendants fraudulently induced state Medicaid formulary committees to place Plavix on their respective state PDLs — or formularies — by marketing Plavix to those committees as more effective than aspirin, when Plavix was not in fact more effective than aspirin. 4AC ¶ 98, n. 140 (incorporating *Thomas* into fraud-in-the-inducement theory). Relator again contends that Plavix therefore did not meet the state-law requirements for cost-effectiveness, a prerequisite to being included on the formularies of the thirty-six states imposing such requirements. The court shall refer to this category of claims as the "Formulary Allegations."

Defendants move to dismiss all of Relator's federal FCA claims in both categories. Specifically, Defendants argue that the Prescriber Allegations must be dismissed because (1) the law of the case bars Relator from reviving federal FCA claims based on alleged implied false certifications submitted in the 19 states and state FCA claims under the statutes of 17 states that this Court dismissed in its decision concerning the 3AC; (2) the Prescriber Allegations are deficient under Fed. R. Civ. P. 9(b); and (3) the Prescriber Allegations fail to meet the heightened pleading standard for materiality established by the Supreme Court in *Escobar*. Defendants argue that the Formulary Allegations must be dismissed because (1) the law

of the case bars Relator from reviving the Formulary Allegations, which were dismissed in this Court's decision concerning the 3AC; and (2) the Formulary Allegations fail to state a claim under *Thomas*, or any other identified authority. Additionally, Defendants move, in the alternative, to dismiss Relator's state FCA claims to the extent based on the retroactive application of the state FCA statutes in five states which became effective after March 30, 2005. I will address each of Defendants' arguments in turn.

A. The Prescriber Allegations

1. Law of the Case

"The law of the case doctrine directs courts to refrain from re-deciding issues that were resolved earlier in the litigation." *Pub. Interest Research Grp. of New Jersey, Inc. v. Magnesium Elektron, Inc.,* 123 F.3d 111, 116 (3d Cir. 1997). The rule was developed "to maintain consistency and avoid reconsideration of matters once decided during the course of a single continuing lawsuit." *In re Pharmacy Benefit Managers Antitrust Litig.,* 582 F.3d 432, 439 (3d Cir. 2009) (internal quotation marks and citation omitted). Law of the case is a matter of a court's discretion, but a court faced with revisiting a prior decision in the case "should be loathe to do so in the absence of extraordinary circumstances such as where the initial decision was clearly erroneous and would make a manifest injustice." *Id.* (quoting *Christianson v. Colt Indus. Operating Corp.,* 486 U.S. 800, 816 (1988)). In addition, a court may revisit its own decisions or one of a coordinate court where (1) new evidence is available; (2) "a supervening new law has been announced"; or (3) "whenever it appears that a previous ruling, even if unambiguous, might lead to an unjust result." *Id.* The law of the case doctrine, however, only applies "to issues that the court actually decided, whether expressly or by implication." *Coca–Cola*

Bottling Co. of Shreveport v. Coca–Cola Co., 988 F.2d 414, 429 (3d Cir. 1993).

Here, Defendants contend that this Court's dismissal of federal FCA claims based on false certifications of compliance with the law of non-Cost Imposed States in *Dickson* III, acts to bar federal FCA claims based on the law of those states in the 4AC. I disagree. "A False Claims Act violation includes four elements: falsity, causation, knowledge, and materiality." *Petratos*, 855 F.3d at 487. In *Dickson* III, this Court dismissed federal FCA claims based on alleged false certifications of compliance with the law of all states except the Cost-Imposed States on the ground that Relator had failed to plead falsity in connection with the non-Cost-Imposed States. Specifically, the 3AC alleged that Plavix was not "medically necessary" and thus was ineligible for reimbursement under the Medicaid plans of various states. With regard to the Cost-Imposed States, Relator had successfully pleaded that in their legal definitions of medical necessity, "the Cost–Imposed States have included not only a cost-based restriction, but rather, . . . have also mandated that the cheaper alternative must be equally effective as Plavix." *In re Plavix Mktg., Sales Practices & Prod. Liab. Litig.*, 123 F. Supp. 3d 584, 611 (D.N.J. 2015). This Court found such restrictions to be consistent with the limitations authorized by Medicaid, and found Relator to have pleaded that Plavix was not an equally cost-effective treatment to aspirin. Accordingly, although Relator had failed to plead falsity on the basis of "medical necessity," this Court held that Relator had adequately alleged, in the Cost-Imposed States, that physicians submitted claims with the implied false certifications that Plavix met state Medicaid cost-effectiveness requirements for reimbursement. For the same reasons, this Court then dismissed the Prescriber Allegations under the state FCAs of every state except the seven that were also Cost-Imposed states.

With regard to the non-Cost-Imposed states, however, the Court found merely that Relator had failed to allege "how those states have defined 'medical necessity'; in other words, there are no allegations relating to the types of restrictions by a state." *Id.* at 610. Accordingly, this Court did not find that the non-Cost-Imposed states did not impose cost-effectiveness requirements as a prerequisite to Medicaid reimbursement, but rather only that there was a total lack of allegations as to the content of the state statutory requirements for reimbursement in those states.

Relator now seeks to raise federal FCA claims on the basis of certifications of compliance with the laws of nineteen (19) of these previously dismissed states on the grounds that their statutory definitions of medical necessity, or other prerequisites to reimbursement, do indeed contain cost-effectiveness requirements, which Relator simply failed to plead in the 3AC. Relator also presents claims under seventeen (17) more state FCAs for states that allegedly also impose cost-effectiveness requirements for Medicaid reimbursement. It is clear that Relator should have sought leave to amend in order to bring such claims. Allowing Relator to bring federal claims for false certifications of compliance with the law of the nineteen previously dismissed states and state claims under the laws of seventeen previously dismissed states, however, does not require this Court to revisit or overturn the reasoning of its previous decision. In reviewing the 3AC, the Court found that only the Cost-Imposed states included allegations that cost-effectiveness was a precondition for Medicaid reimbursement, and the other states lacked any such allegations. In the 4AC, Relator now seeks to supply such allegations for nineteen additional states under the FCA and seventeen additional states under the state FCAs.

"Generally, Rule 15 motions should be granted." *United States ex rel. Customs Fraud Investigations, LLC. v. Victaulic Co.*, 839 F.3d 242, 249 (3d Cir. 2016). In its most recent precedential FCA decision, the Third Circuit reversed a district court's denial of leave to amend, invoking well-settled Supreme Court precedent. "In *Foman v. Davis*, the Supreme Court held that the fundamental purpose of Rule 15 is to allow a plaintiff 'an opportunity to test his claim on the merits,' and although 'the grant or denial of an opportunity to amend is within the discretion of the District Court,' that discretion is abused if it is exercised without giving the plaintiff sufficient opportunity to make her case." *Ibid.* (quoting *Foman v. Davis*, 371 U.S. 178, 182 (1962)). Here, Plaintiff's proposed additional allegations are consistent with the Court's decision in *Dickson* III, and there is no possibility of prejudice to Defendants in considering such allegations as they are equally subject to Defendants' legal challenges under 9(b) and 12(b)(6) as are the allegations concerning the Cost-Imposed States. Moreover, while this Court has certainly afforded Relator ample opportunities to make her case, as demonstrated by its previous grant of leave to amend in *Dickson* II, the Court finds in its discretion that it would not be in the interest of justice or the parties to deny Relator the opportunity to test the legal sufficiency of her claims in the present motion. Defendants' motion to dismiss the federal and state FCA Prescriber Allegations under the law of the case is denied.

2. Rule 9(b)

Defendants next seek reconsideration of their own previously denied motions to dismiss the Prescriber Allegations under Fed. R. Civ. P. 9(b). As this Court observed in *Dickson* III, Chief Judge Herndon, hearing this case in the transferor court prior to its transfer here, denied Defendants' Motion to Dismiss under Rule 9(b). *See* January 2013 Memorandum and Order. With regard to

Defendants' assertions that the Second Amended Complaint was insufficient under Rule 9(b), Chief Judge Herndon stated that "Relator's instant allegations are sufficient to comport with the requirements of Rule 9(b) in this instance," and that "[a]s to which specific physicians such misrepresentations were allegedly made, and further which specific employees of defendants' instructed relator to make such misrepresentations, such details can be fleshed out in discovery." *Id.* at 8–9. In response to Defendants' arguments that "relator is required at this stage in the proceedings to identify specific claims actually submitted which relator alleges were false," the court stated that it "does not feel such specificity is required in this instance." *Id.* at 9 n. 6.

In response to Defendants' renewed motion to dismiss under 9(b) in *Dickson* III, this Court observed that "[w]hile the Third Amended Complaint has added significant details as to the states' limitations on Medicaid and Medicare, . . ., and as to the states' formulary programs, . . ., the factual allegations otherwise remain the same as alleged in the Second Amended Complaint. Thus, with the exception of the Defendants' new arguments regarding the formulary allegations, Chief Judge Herndon's decision regarding the adequacy of Relator's pleading remains the law of the case." *In re Plavix Mktg., Sales Practices & Prod. Liab. Litig.*, 123 F. Supp. 3d 584, 614 (D.N.J. 2015). I next found that none of the extraordinary circumstances warranting reconsideration of the transferor Court's prior decision were applicable and left undisturbed Chief Judge Herndon's decision that Relator's Prescriber Allegations were adequate under Rule 9(b). *Ibid.* I also noted that

> when applying the standard of Rule 9(b) to claims under the FCA, the Third Circuit, like the First, Fifth, and Ninth Circuits, uses a "nuanced" version of the heightened pleading standard. *Foglia*

> *v. Renal Ventures Mgmt., LLC,* 754 F.3d 153, 157 (3d Cir. 2014). Under this reading "it is sufficient for a plaintiff to allege particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." *Id.* at 156. The court also repeated the statement from *Wilkins* that "we ha[ve] never held that a plaintiff must identify a specific claim for payment at the pleading stage of the case to state a claim for relief." *Id.* Thus, Defendants' argument that the Complaint must identify specific false claims is misplaced.

Dickson III, 123 F. Supp. 3d at 614 n. 19.

Looking now to Defendants' present motion, the allegations of the 4AC are substantially similar to the allegations in the 3AC concerning the Prescriber Allegations. Defendants do not dispute this, and instead argue that reconsideration is appropriate because the Supreme Court's decision in *Escobar* constitutes a supervening change in the law governing 9(b) pleading standards for particularity. In *Escobar*, the Supreme Court imposed a heightened pleading standard to allege the element of materiality in implied false certification cases under the FCA. *Escobar*, 136 S. Ct. at 1996. As discussed, *infra*, the decision indisputably states an intervening change of law in the standard to plead materiality under FCA, whether under Fed. R. Civ. P. 8(a) or 9(b). *Escobar*, 136 S. Ct. at 2004 n. 6 ("We reject Universal Health's assertion that materiality is too fact intensive for courts to dismiss False Claims Act cases on a motion to dismiss or at summary judgment. The standard for materiality that we have outlined is a familiar and rigorous one. And False Claims Act plaintiffs must also plead their claims with plausibility and particularity under Federal Rules of Civil Procedure 8 and 9(b) by, for instance, pleading facts to support allegations of

materiality."). *Escobar* is silent, however, whether the general standard for particularity under Rule 9(b) has been affected in the pleading of other FCA elements.

Defendants extrapolate that *Escobar* altered the Rule 9(b) standard for particularity for other FCA elements on the basis of a single line in the decision. *See Escobar*, 136 S. Ct. at 2001 ("we hold that the implied certification theory can be a basis for liability, at least where two conditions are satisfied: first, the claim does not merely request payment, *but also makes specific representations about the goods or services provided*; and second, the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements *makes those representations misleading half-truths*") (emphasis added). Defendants contend that *Escobar*'s requirement of allegations concerning "specific representations about the goods or services provided" and how those representations became "misleading half-truths" changes the particularity pleading requirement of 9(b) for implied certification FCA claims and reopens the inquiry previously decided by the transferor court.

Here, as discussed below, the Court finds the imposition by the Supreme Court in *Escobar* of a heightened pleading standard for materiality under the FCA to be dispositive of Relator's allegations in the 4AC. As such, other than observing that the *Escobar* decision constitutes a supervening change in law with regard to the materiality element, this Court need not decide whether the pleading standard for other elements of the FCA[6] or for

[6] "Rule 9(b)'s heightened pleading standard applies to state law fraud claims asserted in federal court." *N. Am. Catholic Educ. Programming Found., Inc. v. Cardinale*, 567 F.3d 8, 13 (1st Cir. 2009). Accordingly, any change in the general standard for pleading fraud with particularity would affect the state law FCA claims as well.

pleading fraud with particularity under 9(b) have been affected by that decision.[7]

3. Materiality under *Escobar*

As noted above, "[a] False Claims Act violation includes four elements: falsity, causation, knowledge, and materiality." *Petratos*, 855 F.3d at 487. In *Dickson* III, Defendants moved to dismiss, and this Court dismissed the Prescriber Allegations for failure to plead *falsity*, except to the extent raised for implied false certifications of compliance with the law of the 17 Cost-Imposed States. I held:

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[7] This Court's position is supported by the Third Circuit's only decision applying Rule 9(b) to an FCA claim post-*Escobar*. In an unreported decision, the Third Circuit enunciated the heightened pleading standard for implied false certification cases following *Escobar*. "By contrast, implied false certification liability attaches when a claimant '*makes specific representations about the goods or services provided*' and the claimant's 'failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths.'" *United States v. Eastwick Coll.*, 657 F. App'x 89, 94 (3d Cir. 2016) (quoting *Escobar*, 136 S. Ct. at 2001) (emphasis added)). The Third Circuit, then, however, went on to apply the pre-*Escobar* 9(b) pleading standard for particularity to the allegations before it. "In order to satisfy Rule 9(b), a complaint must provide 'all of the essential factual background that would accompany 'the first paragraph of any newspaper story'—that is, the 'who, what, when, where and how' of the events at issue.'" *United States v. Eastwick Coll.*, 657 F. App'x 89, 93 (3d Cir. 2016) (quoting *In re Rockefeller Ctr. Props., Inc. Sec. Litig.*, 311 F.3d 198, 217 (3d Cir. 2002) (quoting *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1422 (3d Cir. 1997))). The Third Circuit also affirmed the continued vitality, post-*Escobar*, of *Foglia v. Renal Ventures Mgmt., LLC*, 754 F.3d 153, 158 (3d Cir. 2014), one of the cases upon which this Court previously relied in denying Defendants' motion for reconsideration of the transferor court's 9(b) ruling in *Dickson* III, applying *Foglia* to the question of whether claims were made with the requisite particularity. *Eastwick*, 657 F. App'x at 95.

> The allegations based on the Medicaid plans of the Cost–Imposed States stand on a different footing. Relator alleges that the Cost–Imposed States have included in their Medicaid statutes a cost effective requirement. In that connection, Relator alleges that Plavix is no more effective than aspirin, which is significantly less costly. *See* TAC at ¶¶ 115–120. Because, as Relator avers, "Plavix was regularly and systematically presented to physicians as superior to aspirin for [certain] patients," *see id.* at ¶ 152, Defendants caused these physicians to submit false claims. At this stage of this litigation, I find that Relator has stated plausible claims under the Cost– Imposed States' Medicaid regime. Relator alleges that cost-effectiveness is a "condition[ ] of Government payment"—that is, a condition "which, if the government knew they were not being followed, might cause it to actually refuse payment." *Wilkins,* 659 F.3d at 309. Indeed, the state statutes and regulations cited by Relator, on their face, indicate that services and treatments must be cost-effective in order to be covered by Medicaid.

Dickson III, 123 F. Supp. 3d at 611. The Court's judgment was rendered with the caveat that "Relator's claims in this context may not survive scrutiny should, for example, evidence show that Plavix was placed on certain states' Preferred Drug Lists," because, as courts in other circuits had observed, prescriptions for drugs on state PDLs may be submitted to and paid by Medicaid without the prescribing physician having to obtain prior authorization from the state — that is, the state payor might not have the opportunity to deny reimbursement for the prescription. *Ibid.* In other words, this Court noted that while on the face of the 3AC, Relator had adequately alleged

that *false* certifications of cost-effectiveness had been submitted, it remained to be determined whether those false certifications were *material* to a government payor's reimbursement decision, in light of the exemption of some drugs from the prior authorization process altogether.

In the 4AC, Relator now affirmatively alleges that every state imposing a cost-effectiveness requirement for reimbursement under Medicaid also placed Plavix on its PDL or formulary, exempting Plavix from all prior authorization requirements, and obligating state Medicaid payors to reimburse claims for Plavix automatically. *See* 4AC ¶¶ 26, 47, 99-150. Defendants contend that, in doing so, Relator has pleaded herself out of court by alleging facts showing that implied false certifications by prescribing physicians necessarily could not have been material to Medicaid's decision to pay for Plavix prescriptions. In short, Defendants contend that Relator has alleged that state Medicaid agencies would reimburse Plavix prescriptions automatically upon receipt because Plavix was included on each state's PDL, regardless of whatever representations were made by the prescribing physician. Defendants contend that these allegations fail the heightened pleading standard for materiality set forth by the Supreme Court in *Escobar*. I agree.

In *Escobar*, the Supreme Court reaffirmed the well-established requirement 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," and sought to "clarify . . . how that *rigorous* materiality requirement should be enforced." 136 S. Ct. at 1996 (emphasis added). The *Escobar* Court explained:

> The materiality standard is demanding. The False Claims Act is not "an all-purpose antifraud statute," or a vehicle for punishing garden-

> variety breaches of contract or regulatory violations. A misrepresentation cannot be deemed material merely because the Government designates compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment. Nor is it sufficient for a finding of materiality that the Government would have the option to decline to pay if it knew of the defendant's noncompliance. Materiality, in addition, cannot be found where noncompliance is minor or insubstantial.

Id. at 2003 (quoting *Allison Engine,* 553 U.S., at 672). The Court later concluded:

> In sum, when evaluating materiality under the False Claims Act, the Government's decision to expressly identify a provision as a condition of payment is relevant, but not automatically dispositive. Likewise, proof of materiality can include, but is not necessarily limited to, evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement. Conversely, if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material. Or, if the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material.

Id. at 2003–04. The Supreme Court also explained that failure to plead materiality was a proper basis for a motion to dismiss. *Id.* at 2004 n. 6 ("We reject Universal Health's

assertion that materiality is too fact intensive for courts to dismiss False Claims Act cases on a motion to dismiss or at summary judgment. The standard for materiality that we have outlined is a familiar and rigorous one."). After offering such guidance on how the materiality standard should be applied, the Court declined to apply it to the facts before it and remanded to the court of appeals for application. *Id.* at 2004.

Significantly, the Third Circuit has recently applied *Escobar* in circumstances which control the outcome in this case. In *Petratos*, the Third Circuit found that *Escobar* imposed a "heightened materiality standard" to plead a violation of the FCA, and applied that standard to affirm the dismissal of a relator's implied false certification complaint. *Id.* at 492–93.[8] The relator in *Petratos* alleged that the defendants, the makers of the widely prescribed cancer drug Avastin, had engaged in a marketing campaign which systematically suppressed information about Avastin's health risks, and "[a]s a consequence of [defendants'] data-suppression strategy, [relator] claimed the company caused physicians to submit Medicare claims that were not 'reasonable and necessary.'" *Petratos*, 855 F.3d at 485–86. The relator further alleged:

> If Roche/Genentech had revealed true and complete clinical, safety, and epidemiological information about Avastin to government regulatory agencies or the public, a significant number of doctors (if not all) would have more carefully evaluated their patients in order to determine which patients should receive lower doses of the

[8] The district court below in *Petratos* dismissed the relator's complaint for failure to plead falsity. The Third Circuit disagreed with the district court's analysis, but affirmed on the alternative basis that the complaint failed to plead materiality, in light of the Supreme Court's intervening decision in *Escobar*. *Petratos*, 855 F.3d at 489.

> drug, or discontinue use of the drug altogether. Similarly, had Roche/Genentech been truthful and forthcoming with reporting this information, third party payers (including federal and state government programs) would have reimbursed for fewer Avastin indications or for lower dosages, or conceivably would not have reimbursed for Avastin treatment at all.

United States ex rel. Petratos v. Genentech, Inc., No. 2:11-CV-03691, First Amended Complaint filed 04/16/15, Dkt. No. 77, ¶ 19. The Third Circuit found that the relator's allegations did not meet the "high standard" for pleading materiality post-*Escobar*.

> 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." 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 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.

Petratos, 855 F.3d at 490 (citations omitted) (emphasis in original). In further support of its finding that the relator failed to plead materiality, the Third Circuit also noted that (i) the mere fact that a drug being "reasonable and

necessary" was a condition of payment, without more, does not establish materiality; (ii) relator failed to plead that CMS "consistently refuses to pay" claims like those alleged; (iii) relator essentially conceded that CMS would consistently reimburse those claims with full knowledge of the purported noncompliance; and (iv) relator failed to cite to a single successful claim under the "reasonable and necessary" provision involving drugs prescribed for their on-label uses or a court decision upholding such a theory. *Id.* at 490.

Here, in the 4AC, Relator baldly alleges that government payors would not have reimbursed for Plavix had they been aware of the alleged false certification of cost-effectiveness,[9] but Relator's other, more specific allegations, belie these conclusory facts because 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. Specifically, Relator first alleges that Plavix was listed on the PDL of every state imposing a cost-effectiveness requirement for reimbursement. *See* 4AC ¶¶ 99-150. Next, Relator alleges that once a claim for Plavix was received by a government payor, it had to be paid automatically because of Plavix's listing on the state PDLs/formularies. *Id.* at ¶ 26 ("For drugs that are on the formulary, Medicaid programs are required to reimburse the cost of a drug on a state's formulary when the drug is prescribed by a physician for an indication for which the drug is on the formulary. Thus, if a drug is on a state's formulary,

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[9] *See, e.g.*, 4AC ¶ 196 ("Had the United States known that BMS/Sanofi were knowingly causing physicians and pharmacists to submit such false claims for payment, the United States would not have provided reimbursement for such prescriptions under Government Payors' programs."); ¶ 208 (same for California); ¶ 222 (same for Colorado); ¶ 234 (same for Connecticut); etc.

once an "on-label" prescription for that drug is written and the prescription is filled, the cost for that prescribed drug is automatically reimbursed by Government Payors. No other authorizations are required."); ¶ 47 ("But because of BMS/Sanofi's fraudulent conduct, prescribing physicians were misled into prescribing Plavix for Medicaid subscribers—which prescriptions certified to the Cost-Imposed States that Plavix met the requirements for Medicaid reimbursement—namely that the drug was medically necessary and cost effective for each patient receiving a prescription for Plavix. Where Plavix is on the formulary, these false certifications resulted in the automatic reimbursement of Plavix.").

Accordingly, the Prescriber Allegations in the 4AC clearly allege that once Plavix was placed on a state PDL, the government payor was obligated to reimburse on-label claims for the drug automatically, without consideration of what certifications the prescribing physicians might or might not have been making about the drug. Accordingly, while the Prescriber Allegations may suggest that Defendants' alleged fraudulent marketing of Plavix to prescribing physicians *caused* allegedly legally false claims to be submitted to Medicaid government payors, the Prescriber Allegations clearly state that the government payors' decision *to pay* the claims was based solely upon Plavix's inclusion on the state PDL.

In the 4AC Relator contends that these allegations are sufficient to establish causation. 4AC ¶ 27 ("A false implied certification by a doctor that a particular drug is medically necessary and cost effective for a particular patient (i.e., a prescription) is not just material to the Government Payor's payment decision, it is determinative because that prescription results in Government Payor reimbursement despite its falsity."). The relator in *Petratos* made a similar argument, which the Third Circuit explicitly rejected. In *Petratos*, as here, the relator argued that

because defendants' fraudulent marketing practices to prescribing physicians were a "but for" cause of the submission of claims including implied false certifications to government payors, in other words that the defendants' misrepresentations to physicians about the drug were material to the physicians' decision to prescribe the drug and submit a claim to Medicare or Medicaid, the defendants' fraud was material to the government payors' decision to reimburse the claims. The Third Circuit succinctly noted that relator's "argument conflates materiality with causation, a separate element of a False Claims Act cause of action." *Petratos*, 855 F.3d at 491. The Third Circuit explained that in the FCA specific context, *the government* is always the "ultimate recipient of the misrepresentation" about compliance with a statutory, regulatory, or contractual requirement," and materiality is judged exclusively in relation to the government's payment decision. *Petratos*, 855 F.3d at 491. The Third Circuit concluded:

> By attempting to focus our inquiry solely on the physician's materiality determination, [relator] 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.

Id. at 492 (emphasis added). Applied here, the prescribing physicians' alleged belief that Plavix was cost-effective on the basis of Defendants' allegedly fraudulent marketing

campaign, is relevant only to the extent that is shows that Defendants induced or caused claims containing implied false certifications of cost-effectiveness to reach the government Medicaid payors. For the Prescriber Allegations to state a claim under the FCA, Relator needed also to allege that the prescribers' implied false certification of cost-effectiveness affected the government Medicaid payors' decision to pay the claims for Plavix. This Relator failed to do, and indeed could not do, instead clearly alleging that once the claims for Plavix were submitted to Medicaid, they were paid automatically by virtue of Plavix's inclusion on state PDLs, without consideration by a government payor of the prescribers' implied certification of cost-effectiveness.

Returning to the language of *Petratos*, the Prescriber Allegations' claims about Defendants' conduct in marketing Plavix to physicians in a fraudulent of misleading manner, allegedly inducing those physicians to submit prescriptions for Plavix to Medicaid, go to "how the [allegedly false] claim makes its way to the government" and therefore are "considered under the causation analysis." *Id.* at 492. "*Materiality analysis begins after a claim has been submitted*," and the only fact alleged to have influenced the government payors' decision to reimburse claims for Plavix in this case is the inclusion of Plavix on the PDLs for all relevant states. *Ibid.* (emphasis added). Once Plavix was listed on the PDLs, the Complaint alleges that prescriptions for Plavix were reimbursed "automatically," regardless of whatever certifications were being made by the prescribing physicians. 4AC ¶ 26.

As was the Court in *Petratos*, this Court is further convinced in its finding that Relator has failed to plead materiality in this case because (i) the mere fact that a drug being "cost-effective" was a condition of payment, without more, does not establish materiality; (ii) Relator failed to plead that government Medicaid payors in fact

consistently refuse to pay claims like those alleged; (iii) Relator's automatic reimbursement allegations essentially concede that government Medicaid payors would consistently reimburse claims for Plavix with full knowledge of the purported false certification of physicians that Plavix was cost-effective (*i.e.* because Plavix prescriptions were automatically reimbursed without being considered for approval by the Medicaid payor once Plavix was placed on the state PDL); and (iv) Relator failed to cite to a single successful claim under the "cost-effectiveness" provisions of the relevant state statutes involving drugs prescribed for their *on-label* uses or a court decision upholding such a theory. *Petratos*, 855 F.3d at 490.

Accordingly, the Prescriber Allegations fail to plead materiality, and therefore do not state a cause of action under the federal FCA. Count I (for substantive violations of the FCA) and Count II (for conspiracy to violate the FCA), to the extent grounded in the Prescriber Allegations, and are therefore dismissed.[10] For the same reasons, the state FCA Prescriber Allegations will also be dismissed as discussed, *infra*.

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[10] Under section 3729(a)(1)(C), the FCA's conspiracy provision, raised in Count II of the 4AC, liability attaches to any person who "conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G)" of that section. Here, as explained, *supra*, the Court has dismissed Relator's substantive FCA claims under the other subsections of Section 3729(a)(1), and therefore Relator's Section 3729(a)(1)(C) conspiracy claim, premised on a conspiracy to violate those other subsections must be dismissed also. *United States ex rel. Petras v. Simparel, Inc.*, 857 F.3d 497, 507 (3d Cir. 2017) (reasons for the dismissal of relator's substantive FCA claim "appl[y] with equal force to the dismissal of [relator's] conspiracy claim); *id* at 507 n. 53 (quoting *Pencheng Si v. Laogai Research Found.*, 71 F. Supp. 3d 73, 89 (D.D.C. 2014) ("'[T]here can be no liability for conspiracy where there is no underlying violation of the FCA.")).

B. The Formulary Allegations

1. Law of the Case

In *Dickson* III, based on Relator's failure to plead falsity, this Court dismissed Relator's Formulary Allegations, then premised on claims that Defendants had misrepresented Plavix to formulary committees as "medically necessary." *Dickson* III, 123 F. Supp. 3d at 612 ("Relator cannot identify any false certification which actually was a prerequisite to payment. Equally deficient, Relator's speculative allegations with respect to Medicaid P & T Committees also do not state a claim. There are simply no allegations how any of Defendants' allegedly false promotional statements were material to, or had any bearing on, the decisions made by these committees."); *id.* at 612-13 (allegations that Defendants' scheme caused states to include Plavix on their state's Medicaid formularies for indications for which Plavix is not medically necessary failed to plead falsity). In their present motion, Defendants contend that this Court's prior dismissal of the Formulary Allegations is law of the case, and bars Relator from bringing its modified Formulary Allegations in the 4AC. I disagree for two reasons.

Firstly, as was the case with the Prescriber Allegations, the Formulary Allegations in the 4AC are based on Defendants' alleged inducement of state formulary committees to include Plavix on their PDLs through misrepresentations about Plavix's cost-effectiveness, not its medical necessity. As such, Relator's Formulary Allegations in the 4AC do not contradict or otherwise require reconsideration of this Court's previous dismissal of the Formulary Allegations in the 3AC based on Plavix's medical necessity. Although, again, it would have been appropriate for Relator to request leave to amend to conform her Formulary Allegations to this Court's prior decision, the Court grants such leave now in the interest of allowing Plaintiff an opportunity for her claims to be considered

fully and because of the absence of prejudice to Defendants. As with the Prescriber Allegations, Defendants have had an opportunity to move to dismiss the Formulary Allegations as presently drafted, and indeed have done so.

Secondly, the 4AC makes clear, for the first time, that Relator's formulary allegations are intended to state a claim under a fraud-in-the-inducement theory of liability under the FCA, as embodied in the Third Circuit's unreported decision in *Thomas*. 4AC ¶ 98, n. 140. Because a fraud-in-the-inducement theory of liability was not before this Court in *Dickson* III, and the Court did not have the benefit of the parties' briefing on the issue, the Court, in its discretion, declines to hold that the Court's prior dismissal of the Formulary Allegations encompassed Relator's new theory. Accordingly, Defendants' motion to dismiss the Formulary Allegations as law of the case is denied, and I will now turn to the merits of the claim.

2. Rule 12(b)(6) Failure to State a Claim

As discussed, *supra*, the Prescriber Allegations in the 4AC fail because they allege that state formulary committees' decisions to include Plavix on their state PDLs, and not the implied false certifications of prescribers submitting claims to Medicaid, were actually material to government Medicaid payors' decisions to reimburse claims for Plavix. In other words, the allegedly fraudulent inclusion of Plavix on a PDL by a formulary committee, not the submission of a false claim by a physician, is the operative act affecting each Medicaid payment decision in this case. The question before the Court on Relator's Formulary Allegations, therefore, is whether the FCA recognizes such a cause of action for "fraud on the formulary committee." Relator, in the 4AC, and in her opposition briefing on the present motion, contends that the FCA does provide for such actions under the theory of fraud in the inducement enunciated in *Thomas*.

"[T]he focus of the False Claims Act is on false 'claims.'" *Thomas*, 593 F. App'x at 143. "The conception of a claim against the government normally connotes a demand for money or for some transfer of public property." *Hutchins v. Wilentz, Goldman & Spitzer*, 253 F.3d 176, 183 (3d Cir. 2001) (quotation omitted). *See also id.* (quoting *United States v. McNinch*, 356 U.S. 595, 599 (1958) ("the False Claims Act was not designed to reach every kind of fraud practiced on the Government"). In *Thomas*, however, relying upon older, reported precedent, the Third Circuit held that "[a]lthough the focus of the False Claims Act is on false 'claims,' courts have employed a fraudulent inducement theory to establish liability under the Act for each claim submitted to the government under a contract which was procured by fraud, even in the absence of evidence that the claims were fraudulent in themselves." *Thomas*, 593 F. App'x at 143. This theory dates back to the decision of the Supreme Court in *United States ex rel. Marcus v. Hess*, 317 U.S. 537 (1943) (superseded by statute). *See id.* at 542–44 (recognizing fraudulent inducement theory). *Hess* involved collusive bidding on federally assisted state contracts. The United States later made payments by disbursing federal grants into a joint fund to aid the local government in paying its obligations under the collusively obtained contracts. The Supreme Court noted that although the wrongdoing in *Hess* did not involve the submission or inducement of a false claim in the strictest sense, the conduct of the defendants in inducing the underlying contracts by fraud nevertheless fell within the prohibition of the FCA.

> The government's money would never have been placed in the joint fund for payment to respondents had its agents known the bids were collusive. By their conduct, the respondents thus caused the government to pay claims of the local sponsors in order that they might in turn pay

> respondents under contracts found to have been executed as the result of the fraudulent bidding. This fraud did not spend itself with the execution of the contract. Its taint entered into every swollen estimate which was the basic cause for payment of every dollar paid by the P.W.A. into the joint fund for the benefit of respondents. The initial fraudulent action and every step thereafter taken, pressed ever to the ultimate goal—payment of government money to persons who had caused it to be defrauded.

Hess, 317 U.S. at 543–44. The Third Circuit has long applied *Hess*'s holding. *See United States v. Veneziale,* 268 F.2d 504, 505 (3d Cir. 1959) ("[I]t has long since been settled that a fraudulently induced contract may create liability under the False Claims Act when that contract later results in payment thereunder by the government…"). Furthermore, when Congress amended the FCA in 1986, it recognized that fraudulently induced contract claims were actionable under the statute. S. Rep. No. 99–345, at 9 (1986), *reprinted in* 1986 U.S.C.C.A.N. at 5266, 5274 ("[E]ach and every claim submitted under a contract, loan guarantee, or other agreement which was originally obtained by means of false statements or other corrupt or fraudulent conduct, . . . constitutes a false claim.").[11] Since the 1986 Amendments, numerous federal Courts of Appeals have recognized the "fraud-in-the-inducement" theory of FCA liability in the context of *contracts* induced by fraud.[12]

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[11] The district court below in Thomas relied in part on the legislative history of the 1986 Amendments in finding an actionable "fraud-in-the-inducement" claim in that contract case. *U.S. ex rel. Thomas v. Siemens AG*, 991 F. Supp. 2d 540, 567–68 (E.D. Pa.), *aff'd*, 593 F. App'x 139 (3d Cir. 2014).

[12] *See, e.g., In re Baycol Prod. Litig.*, 732 F.3d 869, 876 (8th Cir. 2013) ("when a relator alleges liability under a theory of fraud-in-the

a) The Third Circuit Has Not Recognized Relator's Theory of FCA Liability

Here, Relator argues that the fraud-in-the-inducement theory in *Thomas* may be extended to support Relator's fraud-on-the-formulary-committee theory in this case. I disagree. Firstly, none of the Supreme Court or circuit court precedents recognizing the fraud-in-the-inducement theory, including those binding decisions of the Third Circuit, has ever recognized Relator's novel fraud-on-the-formulary-committee theory. Fraud-in-the-inducement began in the Supreme Court's *Hess* decision as a doctrine applicable to contracts induced by fraud. It was reaffirmed by Congress in the legislative history of the 1986 Amendments to the FCA as a doctrine limited to claims "under a contract, loan guarantee, or other agreement." S. Rep. No. 99–345, at 9 (1986), *reprinted in* 1986

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inducement, claims for payment subsequently submitted under a contract initially induced by fraud do not have to be false or fraudulent in and of themselves in order to state a cause of action under the FCA"); *United States ex rel. Longhi v. Lithium Power Techs., Inc.,* 575 F.3d 458, 467–68 (5th Cir. 2009) (where a contract was procured by fraud, even when subsequent claims for payment under the contract were not literally false, they became actionable FCA claims because they "derived from the original fraudulent misrepresentation"); *Wilson v. Kellogg Brown & Root, Inc.,* 525 F.3d 370, 376 (4th Cir. 2008) (recognizing a fraudulent inducement claim under the FCA based on obtaining a government contract through false statements) (citing *Harrison I,* 176 F.3d at 787); *United States ex rel. Hendow v. Univ. of Phoenix,* 461 F.3d 1166, 1173 (9th Cir. 2006) ("liability will attach to each claim submitted to the government under a contract, when the contract ... was originally obtained through false statements or fraudulent conduct"); *United States ex rel. Bettis v. Odebrecht Contractors of Cal., Inc.,* 393 F.3d 1321, 1326 (D.C. Cir. 2005) ("[C]ourts have employed a 'fraud-in-the-inducement' theory to establish liability under the Act for each claim submitted to the Government under a contract which was procured by fraud, even in the absence of evidence that the claims were fraudulent in themselves.") (citation omitted).

U.S.C.C.A.N. at 5266, 5274. And it has only ever been applied by the Courts of the Third Circuit, including in *Thomas* itself, to contracts induced by fraud. *Thomas*, 593 F. App'x at 143 (allegations that defendants fraudulently induced the VA to enter into the contracts); *States v. Veneziale*, 268 F.2d 504, 505 (3d Cir. 1959) (allegations that defendants fraudulently induced government guaranteed bank loan agreement). In the absence of any binding or persuasive authority suggesting that a theory of liability formed in the context of contracts should be applied equally in the context of non-contract interactions with government regulatory bodies, as in this case, marketing statements to formulary committees, this Court will not craft a fraud-on-the-formulary theory for Relator out of whole cloth.

Secondly, even were the Court inclined to reason by analogy from the contract context, *Thomas* would still not offer Relator a cause of action here. In *Thomas* and the earlier fraud-in-the-inducement cases going back to *Hess*, the fraudulently obtained contract was alleged to give rise to the claims submitted for payment to the government. *See, e.g.*, *Hess*, 317 U.S. at 543 (award of contracts induced local government sponsors to submit claims to the federal government in order to pay defendants under the contracts). Here, Relator cannot allege in the same way that Plavix's listing on state PDLs gave rise to the later claims submitted for payment to the government. Instead, Relator attempts to establish the connection between the fraud on the formulary committee and the payment by the government of false claims through Defendants' alleged separate fraud — although a part of an overall fraudulent scheme — to falsely market Plavix to prescribing physicians, who were thereby induced to submit false claims to Medicaid. The absence of the same direct causal connection between Defendants' alleged fraud on the formulary committee, and the submission of false claims that is

present between contracts induced by fraud and claims submitted under those contracts, gives the Court pause because it suggests that embracing Relator's theory would be a step toward bringing all misrepresentations to government bodies within the purview of the FCA. The Supreme Court and the Third Circuit have always made it clear that the FCA was not designed to have so expansive a scope. *See, e.g.*, *Escobar*, 136 S. Ct. at 2003 (quoting *Allison Engine,* 553 U.S., at 672) ("The False Claims Act is not 'an all-purpose antifraud statute'"); *Petratos*, 855 F.3d at 490 (quoting *Wilkins*, 659 F.3d at 307 (citation omitted)) ("the False Claims Act is not 'a blunt instrument to enforce compliance with all . . . regulations.'"); *Wilkins*, 659 F.3d at 307 ("the implied certification theory of liability should not be applied expansively, particularly when advanced on the basis of FCA allegations arising from the Government's payment of claims under federally funded health care programs. In particular . . . the rationale . . . does not fit comfortably into the health care context because the [FCA] was not designed for use as a blunt instrument to enforce compliance with all medical regulations—but rather only those regulations that are a precondition to payment." (citation omitted)). Accordingly, this Court will not extend the Third Circuit's recognized fraud-in-the-inducement theory of FCA liability beyond the realm of contracts induced by fraud.

b) The *Solvay* Decision is Unpersuasive

In opposition, Relator cites to a single reported case for the proposition that *Thomas* may be extended to encompass a fraud-on-formulary-committee theory of liability.[13] Relator contends that in *U.S. ex rel. King v. Solvay*

[13] Relator also cites two additional unreported cases in support of her position. Both are irrelevant to the Court's analysis. In addition to being a non-binding decision, *United States v. Pfizer, Inc.*, No. 05-CV-6795, 2016 WL 807363, at *10 (E.D. Pa. Mar. 1, 2016), is factually

S.A., 823 F. Supp. 2d 472 (S.D. Tex. 2011) *order vacated in part on reconsideration*, No. 06-CV-2662, 2012 WL 1067228 (S.D. Tex. Mar. 28, 2012), the Sothern District of Texas applied a *Thomas*-like theory to find fraudulent marketing of a drug to a state formulary committee actionable under the FCA. Opp. 26-27.[14]

In *Solvay*, the relators alleged that defendants had marketed three drugs — Luvox, Aceon, and AndroGel — for conditions other than conditions for which the drugs were approved by the FDA ("off-label") and had offered kickbacks to physicians who prescribed the drugs. *Solvay*, 823 F. Supp. 2d at 480-81. The relators in *Solvay* pursued a false certification theory of liability under the FCA, along with claims under the Anti-Kickback Statute. *Solvay*, 823 F. Supp. 2d at 488. In ruling on defendants'

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and legally inapplicable to the present case. Firstly, it was not a fraud-in-the-inducement case; the Relator in *Pfizer* proceeded under an implied false certification theory that doctors were caused by Defendants to submit prescriptions for off-label uses that were not medically accepted or medically necessary. Secondly, *Pfizer* dealt with an alleged scheme for off-label promotion of a drug to *hospital* formulary decision-makers. Simply put, *Pfizer* offers no guidance as to whether Relator has stated a *fraud-in-the-inducement* cause of action for *on-label* promotion to *state formulary committees*. Similarly, in *U.S. ex rel. Brown v. Celgene Corp.*, No. 10-CV-3165, 2014 WL 3605896, at *6 (C.D. Cal. July 10, 2014), the district court found, *inter alia*, a defendant's attempt to improperly influence drug compendia by bribing physicians who worked on the compendia committee to give rise to a plausible inference that the defendant was promoting off-label uses of its drug that were not supported by the compendia. Here, the only uses of Plavix alleged to have been promoted were on label and there are no allegations of bribery.

[14] The Court devotes significant attention to the otherwise only marginally relevant opinion of *Solvay*, because it is the only case that Relator has identified, and that this Court has been able to discover, that may even arguably be said to have adopted Relator's theory of FCA liability. Relator thus relies heavily upon *Solvay* in her Opposition and supplementary briefing.

motion to dismiss the realtors' FCA claims pursuant to Fed. R. Civ. P. 12(b)(6), the *Solvay* Court first found that for at least some of the drugs, relators had shown off-label claims had knowingly been submitted for payment to the government. *Id.* at 509. The Court then proceeded to consider whether the relators' false certification FCA claims satisfied the elements of falsity and materiality. Turning to materiality first, the court concluded, without reasoning or supporting law, that relators' false certification claims for off-label promotion satisfied the FCA's materiality requirement.[15] *Id.* at 509. The court then launched into an extensive analysis of the falsity element, focused on whether the drugs which had been marketed off-label were nevertheless marketed for a medically accepted use

[15] It is worth noting that the *Solvay* Court employs confused and vague language, which makes it impossible for this Court to determine the basis on which materiality was initially found. For example the Court, referencing its discussion of Rule 9(b) particularity wrote "the court found above that the alleged off-label promotion was material to off-label claims, under subsection 3729(a)(1)." *Id.* at 509. As the Third Circuit made clear in *Petratos*, however, the inquiry in FCA false certification cases is not whether defendants' marketing efforts are material to the submission of claims, but rather whether the ultimate false certification that reaches the government is material to the government's payment decision. Moreover, the *Solvay* court's opinion is unclear whether materiality was ever really at issue on defendants' motion. The *Solvay* Court first wrote that "[defendant] SPI moves to dismiss the 4AC under Rule 12(b)(6) because it fails to plead falsity or materiality as to the alleged FCA violations based on off-label promotion." *Id* at 509. Just sentences later, however, the court wrote "[defendant] SPI's argument here, though, is not that the alleged scheme was not material to off-label claims. Rather, SPI argues that Relators fail to allege facts demonstrating that off-label claims stemming from the alleged off-label promotion were non-reimbursable, and therefore false, claims." *Ibid.* In short, immediately after stating that materiality was at issue, the *Solvay* court stated that the defendant's motion really sounded in falsity.

listed in the DrugDex compendium. The *Solvay* Court concluded that the realtors had alleged falsity.

After addressing these two elements, the *Solvay* court moved on to a new subsection of its opinion, confusingly titled "Alternative Ways of Showing Falsity/Materiality." I so characterize the title because, the federal courts have not recognized "alternative ways" to demonstrate falsity or materiality than those reflected in the Medicare and Medicaid statutes and case law that the *Solvay* court had already addressed, and secondly, because falsity and materiality are distinct elements of an FCA claim, which cannot be used and should not be referred to interchangeably. Tellingly, it is this section of the Solvay court's opinion upon which the Relator in this case relies. The *Solvay* court first concluded, without citation to supporting law, that:

> Linking the off-label promotion to materially false claims with claims data is not the only way in which the 4AC could allege that the prescriptions resulting from the off-label promotion had a natural tendency to influence the government's decision regarding payment of claims. Relators argue that . . . [defendant's] specific targeting of P & T committee members to gain favorable treatment on state formularies demonstrate that the off-label promotion campaign had a natural tendency to influence the government's decision regarding payment of claims.

Solvay, 823 F. Supp. 2d at 514.

The *Solvay* court then discussed the allegations in the realtors' complaint supporting this "alternative" theory of materiality:

> The 4AC additionally alleges that Solvay specifically geared its off-label promotion towards members of state P & T committees in a [sic]

> attempt to influence which drugs were included on the states' Medicaid formularies. The 4AC alleges that "[w]ooing P & T committee members was discussed openly and earnestly on periodic conference calls with upper management." A Solvay sales representative allegedly argued for the inclusion of Aceon on the Preferred Drug List in a meeting with the West Virginia P & T Committee. She allegedly relied on the PROGRESS study, which the 4AC alleges does not support the use of Aceon at all.

Id. at 515 (citations omitted).

Then, once again without the discussion of any law, the *Solvay* court summarily concluded that "the alleged wooing of P & T committee members plausibly influenced which drugs were placed on state formularies and thus had a natural tendency to influence the states' decision, and in turn the federal government's, decision with regard to payment. Accordingly, the 4AC plausibly satisfies the materiality element." *Ibid.* Finally, after another brief discussion about falsity, the court concluded "[i]n sum, the court finds that the 4AC plausibly pleads that the claims resulting from off-label promotion were false *or* material." *Ibid.* (emphasis added). I am particularly troubled by this conclusion because, to state an FCA claim, the alleged false certification must be both false *and* material.

As a threshold matter, I note that *Solvay* is an out-of-circuit, district court decision which is not binding on this Court. I further find that I cannot place any reliance upon it as persuasive authority due to the gaps in its reasoning identified, *supra*, and its complete failure to cite any law in reaching the holding for which Relator offers it to this Court. The *Solvay* Court did not adequately distinguish between falsity and materiality, nor did it appropriately address the principle that materiality is judged from the perspective of the government payor, not the physician

submitting an allegedly false claim. Moreover, *Solvay*, as every other case cited by Relator in support of her Formulary Allegations, involved the *off-label* marketing of drugs. *Solvay*, 823 F. Supp. 2d at 515 ("specifically geared its off-label promotion towards members of state P & T committees"). The 4AC alleges, and there is no dispute in this case, that Defendants' alleged marketing efforts to state formulary committees, to the extent they existed at all, were strictly for on-label, FDA-approved indications of Plavix. An open question thus remains whether *Solvay* and Relator's other off-label cases have any import here at all. *See, e.g.*, *Petratos*, 855 F.3d at 490 (observing in dismissing relator's claim, "[n]or has he cited to a single successful claim under [Medicare's exclusions from coverage] involving drugs prescribed for their on-label uses or a court decision upholding such a theory."). Based upon the foregoing, I find that *Solvay* provides no persuasive support for Relator's position here.

There are further reasons that *Solvay* does not assist Relator's case. Firstly, *Solvay* is not, as Relator argued, a fraud-in-the-inducement case like *Thomas*. Instead, it appears that the court, after proceeding through the elements of an FCA claim on defendants' motion to dismiss, hypothesized about other "alternative" ways in which the relators in that case could have established the elements of falsity and materiality in their false certification claim. The court then, concluded, without legal citation, that allegations of a fraud on state formulary committees satisfied the materiality element in a false certification FCA case. One possible explanation for this result can be found in the legal standard the *Solvay* court identified earlier in its opinion. There, the court indicated that it considered the realtors' claims under the framework set forth by the Fifth Circuit in *United States ex rel. Longhi v. United States,* 575 F.3d 458, 470 (5th Cir. 2009). *Longhi*, a *pre-Escobar* case, established a "natural tendency" test for

materiality in the Fifth Circuit. "The 'natural tendency' test requires 'that the false or fraudulent statements either (1) make the government prone to a particular impression, thereby producing some sort of effect, or (2) have the ability to effect the government's actions, even if this is the result of indirect or intangible actions on the part of the Defendants.' Thus, the statements must 'have the potential to influence the government's decisions.'" *Solvay*, 823 F. Supp. at 489–90 (quoting *Longhi,* 575 F.3d at 470). This test for materiality is significantly more permissive and expansive of the FCA's scope than the materiality test established in *Escobar* and applied in *Petratos*.

Although the Fifth Circuit has yet to explain whether *Escobar* overturned *Longhi*, in a recent reported decision, the Court of Appeals cited *Longhi* for the elements of an FCA claim, but applied *Escobar*'s heightened pleading standard for materiality. *See Abbott v. BP Expl. & Prod., Inc.*, 851 F.3d 384, 387–88 (5th Cir. 2017) (referencing *Longhi*, but applying *Escobar* instead of the "natural tendency" test). At least one circuit court of appeals has specifically considered the issue, and has concluded that *Longhi* and its equivalents in other circuits are not good law after *Escobar*.[16] Although this Court need not decide

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[16] *See Johnson v. D.C.,* 144 A.3d 1120, 1136-1138 (D.C. 2016) (seven circuits, including the Fifth Circuit in *Longhi*, adopted the less burdensome "natural tendency" test for materiality in FCA cases; the Eighth Circuit adopted an "outcome materiality test" holding that there can be no false claim if the government would have made payments regardless of the defendant's actions; in *Escobar* "the Court announced a new approach to materiality closer to the outcome test than to the less stringent one followed by a majority of the federal circuits. . . . The statutory test for 'materiality,' therefore, as 'having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property,' appears to be 'the effect on the *likely or actual* behavior of the recipient of the alleged misrepresentation' upon learning about it, not on its mere potential to affect the recipient's decision.").

the issue, having already determined that *Solvay* is not entitled to any persuasive weight, the very fact that *Solvay* is not based on current law further undercuts its relevance to Relator's proposed legal theory.

c) Comparable Fraud-on-the-FDA Claims Have Been Rejected

Finally, I note that, although not discussed by the parties, Relator's Formulary Allegations more closely resemble unsuccessful FCA actions for "fraud-on-the-FDA," which have, on rare occasions, been raised in this and other federal district courts. Relator fares no better under the reasoning of those cases. Relators there alleged that 1) defendants committed fraud in obtaining FDA approval for their drugs, through deceptive statements or the withholding of relevant information, 2) claims for those drugs were submitted to and paid by government payors, 3) government payors relied upon the drugs' FDA approval in making their decision to pay, and therefore 4) all claims paid by the government payors were converted to false claims by virtue of the fact that FDA approval was obtained by fraud.[17] Here, the Formulary Allegations

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[17] *See, e.g.*, *U.S. ex rel. Feldstein v. Organon, Inc.*, No. CIVA.07-CV-2690(DMC), 2009 WL 961267, at *11 (D.N.J. Apr. 7, 2009), *aff'd*, 364 F. App'x 738 (3d Cir. 2010) ("Nonetheless, Relator's claim is that Defendants committed fraud when it obtained approval of Raplon® and as a result, all claims for payments from the Government for Raplon® were illegitimate. The fraud at issue allegedly took place when Organon obtained approval for Raplon® and not when claims were submitted to the Government."); *United States ex rel. D'Agostino v. EV3, Inc.*, 153 F. Supp. 3d 519, 538–39 (D. Mass. 2015), *aff'd sub nom. D'Agostino v. ev3, Inc.*, 845 F.3d 1 (1st Cir. 2016) ("In broad generalizations, D'Agostino alleges that all Axium devices on the market were defective and therefore, any claim for Medicare reimbursement involving Axium was false. With regard to Onyx, D'Agostino returns repeatedly to the theme that, but for defendants' misrepresentations, the FDA would not have approved Onyx in the first instance. In another iteration of this argument, D'Agostino speculates that, had the

state an analogous case, namely that Defendants fraudulently induced state formulary committees to place Plavix on their respective state PDLs, which resulted in the automatic reimbursement by government payors of false claims for Plavix submitted by prescribers.

In the wake of *Escobar*, the First Circuit Court of Appeals in *D'Agostino v. ev3, Inc.*, 845 F.3d 1 (1st Cir. 2016), became the first federal appellate court to consider a "fraud-on-the-FDA" FCA theory on the merits, and soundly rejected it as outside the scope of the statute.[18] I find the First Circuit's opinion persuasive that Relator's fraud-on-the-formulary-committee theory similarly fails and should be dismissed. In *D'Agostino*, the relator claimed that defendants made fraudulent representations to the FDA in seeking approval for their medical device, the device was approved, and Medicare later made payments reimbursing the cost of the device in reliance upon the device's FDA approval. *Id.* at 7. The First Circuit observed that because CMS and not the FDA actually paid all claims in the case and FCA liability attaches to "false or fraudulent claims for payment," relator was required to allege a causal link between the CMS payments and the alleged fraudulent representations made to the FDA. *Id.* at 7. The relator alleged that FDA approval is a precondition to CMS reimbursement for medical devices and that the misrepresentations to the FDA "could have" influenced the FDA to grant approval that it otherwise would not have. *Ibid.*

FDA known of all of the alleged hidden defects, it would have withdrawn its approval of Onyx or ordered its recall.").

[18] The Third Circuit in *U.S. ex rel. Feldstein v. Organon, Inc.*, 364 F. App'x 738 (3d Cir. 2010), was presented with the dismissal of a fraud-on-the-FDA theory by the district court below for failure to plead fraud under Rule 9(b), but affirmed dismissal on other grounds without considering the theory's viability under the FCA.

The First Circuit rejected the relator's allegations as insufficient to plead a violation of the FCA on three grounds, with the third playing the decisive role in the Court's decision. First, the Court noted that the relator's complaint failed to plead causation on its face because the allegations that defendants' fraudulent representations "could have" influenced the FDA were plainly not the same as alleging that the representations *did* influence the FDA and thereby cause the FDA to grant approval and cause CMS to pay false claims on the basis on that approval. *Ibid.* This facial deficiency is not an issue in the 4AC, because Relator has included at least conclusory allegations that the state formulary committees *would not* have listed Plavix on their PDLs had they been aware of Defendants' alleged misrepresentations about Plavix's efficacy relative to aspirin.

Second, the First Circuit noted that the relator argued, relying on 31 U.S.C. § 3729(b)(4), that the fraudulent misrepresentations to the FDA were nevertheless material to CMS's payment decision because they had a "natural tendency to influence" or were "capable of influencing, the payment or receipt of money or property." *Id.* The First Circuit observed that the relator's argument likely misconstrued the FCA's "demanding" materiality standard after *Escobar*. The court then went on to note that "[m]oreover, the FCA requires that the fraudulent representation be material to the government's payment decision itself. The fact that CMS has not denied reimbursement for Onyx in the wake of D'Agostino's allegations casts serious doubt on the materiality of the fraudulent representations that D'Agostino alleges." *D'Agostino*, 845 F.3d at 7 (citing *Escobar* 136 S. Ct. 2003-04 ("[I]f the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are

not material.")). The same concerns about materiality arise in this case because of the 4AC's failure to plead that any government Medicaid payor actually stopped reimbursing for Plavix or took other remedial action in the wake of gaining actual knowledge of the allegations of fraud-on-the-formulary committees[19] in this very-well-publicized, high-profile litigation.[20]

Third and finally, however, the First Circuit in *D'Agostino* found that while materiality might have been lacking, the separate FCA element of causation could not be alleged in the relator's fraud-on-the-FDA theory as a matter of law. *D'Agostino*, 845 F.3d at 8 ("The defect in D'Agostino's claim is not a mere flaw in the complaint's choice of words."). The First Circuit found that the relator's complaint failed to allege that in the six years since the relator first revealed the alleged fraud the FDA had undertaken any action to revoke or reconsider the approval of defendants' device. *Ibid.* The court concluded that

> [t]he FDA's failure actually to withdraw its approval of Onyx in the face of D'Agostino's allegations precludes D'Agostino from resting his

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[19] The Seventh Circuit, the circuit of the transferor court in this case, recently came to a similar conclusion. *United States v. Sanford-Brown, Ltd.*, 840 F.3d 445, 447–48 (7th Cir. 2016) (explaining, on remand from *Escobar*, that materiality looks to the effect on the *likely* or *actual* behavior of the recipient of the alleged misrepresentation, and affirming the grant of summary judgment to defendants where Relator alleged only that the government was legally entitled to deny payment on the basis of defendants' regulatory noncompliance, but failed to show that the government in fact administered penalties or terminated payment upon receiving actual knowledge of the alleged fraud (quotations omitted) (emphasis in original)).

[20] Relator's arguments that government payors and state formulary committees might lack actual knowledge of the alleged fraud are unconvincing, particularly as the Relator admits, roughly half of all state attorney general offices are active participants in the litigation.

> claims on a contention that the FDA's approval was fraudulently obtained. To rule otherwise would be to turn the FCA into a tool with which a jury of six people could retroactively eliminate the value of FDA approval . . . . The FCA exists to protect the government from paying fraudulent claims, not to second-guess agencies' judgments about whether to rescind regulatory rulings.

D'Agostino, 845 F.3d at 8. In short, the court found that the regulatory agency's real-world conduct after having obtained actual knowledge of the fraud must be alleged as evidence in any FCA fraud-on-the-agency style claim because failure to do so would require the court to reconsider and potentially reverse the agency's regulatory ruling on a basis that the agency itself explicitly has chosen not to act upon. The First Circuit was also persuaded in its position by problems in the implementation of any alternative standard for FCA causation in such cases.

> Practical problems of proof also inform our conclusion. How would a relator prove that the FDA would not have granted approval but for the fraudulent representations made by the applicant? Would competing experts read someone's mind? Whose? What if former officials no longer in government were of one view, and current officials of another? These and similar questions all support our position that the absence of some official agency action confirming its position and judgment in accordance with the law renders D'Agostino's fraud-on-the-FDA theory futile.

Id. at 9.

The same considerations arise in this case in the context of Relator's attempt to have this Court second guess the decisions of state formulary committees to list Plavix on their respective states' PDLs. The 4AC does not allege

that any state formulary has delisted Plavix in the wake of this litigation. Were Relator ultimately to prevail on her Formulary Allegations in this case, the jury would have to have find that defendants' alleged misrepresentations to formulary committees *caused* those committees to list Plavix and that the committees would not have listed Plavix on their state PDLs in the absence of those misrepresentations, despite the fact that once the formulary committees themselves actually became aware of the alleged misrepresentations, they took no action to reverse their prior decision. The problems of proof also weigh heavily upon this Court. In the only specific incident of alleged misrepresentations to formularies in the Complaint, a representative from Sanofi is alleged to have spoken during the public comment period during an Idaho formulary committee meeting and misrepresented the results of a clinical trial. 4AC ¶¶ 94, 95. Relator alleges, without specific factual support that "[b]ased on this information, the committee approved Plavix for inclusion on the formulary." 4AC ¶ 96. As in *D'Agostino*, questions arise as to whether present and former formulary committee members who made the Plavix PDL listing determination in Idaho, and every state, would need to be deposed and brought to testify at trial, or competing experts would hypothesize about what an objective physician or pharmacist member of a formulary committee schooled in the applicable state of the art at the time Plavix was considered for listing would have done with knowledge of the alleged fraud, or even which committee members from which time periods opinions should be afforded decisive weight, given that Plavix could have been listed or delisted at any time between its entry into the market and the revelation by Relator of the alleged fraud. In short, although it is sufficient for this Court to observe that Relator's fraud-on-the-formulary committee (or fraud-in-the-inducement) claim does not conform to any theory of FCA liability recognized by the Third Circuit, the Court is persuaded that

the analogy to the First Circuit's rejection of "fraud-on-the-FDA" theories of FCA liability for failure to plead causation in the absence of some agency action, provides further support for this conclusion.

Accordingly, Relator's Formulary Allegations in the 4AC do not state a claim for fraud- in-the-inducement or other cause of action under the federal FCA, and Counts I and II of the 4AC are dismissed. For the same reasons, the state FCA Prescriber Allegations will also be dismissed as discussed, *infra*.

C. State FCA Claims

In *Dickson* III, this Court dismissed the state FCA Prescriber and Formulary Allegations in parallel with their federal counterparts. In their present motion to dismiss the 4AC, Defendants argue that "Relator's claims under . . . the false claims and Medicaid claims statutes of the 24 Participating States are substantively similar to and/or track the language of the federal FCA[,] [and that] [t]hese claims must be dismissed, as they were before, for all the reasons set forth above." Mot. 17. Relator acknowledges that her claims under the state FCAs are subject to the same reasoning as those under the federal FCA, and opposes on the same grounds. Opp. 34 ("Defendants incorporate their FCA arguments in moving for dismissal of Relator's state-law claims. These claims survive for the reasons stated above [in the context of the federal FCA]."). In light of the briefing of the parties applying their arguments under the federal FCA to the twenty-four state FCAs, this Court concludes that the same reasons stated above for the dismissal of Counts I and II — under both the Prescriber and Formulary Allegations — compel dismissal of the state FCA claims, Counts III through XXVI.

Finally, in their Motion, Defendants identify five state false claims acts under which Relator brings suit

which became effective after March 30, 2005, the date to which the Court found Relator's claims to extend under the applicable statutes of limitations, and move to limit these claims to conduct taking place after the statutes' effective dates. The Court having dismissed the state FCA claims, Defendants' motion to restrict the retroactive effect of these five statutes is denied as moot.[21]

V. CONCLUSION

For the reasons stated above, the Defendants' Motion to Dismiss the 4AC is GRANTED, and Defendants' motion to restrict the retroactive application of the five state FCAs, which became effective after March 30, 2005, is denied as moot.

Dated: 6/27/2017

/s/ Freda L. Wolfson
The Honorable Freda L. Wolfson
United States District Judge

[21] In any event, Relator consented to the relief requested in Defendants' non-retroactivity motion. Opp. 35 n. 51.

APPENDIX L

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

In re PLAVIX MARKETING, SALES PRACTICE AND PRODUCTS LIABILITY LITIGATION (NO. II)	MDL DOCKET NO. 2418
UNITED STATES OF AMERICA, *et al.*, ex rel. ELISA DICKSON, Plaintiffs, v. BRISTOL-MYERS SQUIBB CO., *et al*, Defendants.	Civil Action No. 13-1039 (FLW) (LHG) **AMENDED ORDER**

THIS MATTER having been opened to the Court by Lowenstein Sander LLP (Gavin J. Rooney, Esq., appearing), counsel for Defendants Bristol-Myers Squibb Company, Sanofi- Aventis U.S. LLC, Sanofi US Services Inc., and Sanofi-Synthelabo, Inc. ("Defendants"), on a motion to dismiss the Fourth Amended Complaint ("4AC") of Relator Elisa Dickson ("Relator"); it appearing that Relator, through counsel Christopher Cueto, Esq., opposes the motion; the Court having reviewed the submissions of the parties in connection with the motion; pursuant to Fed. R. Civ. P. 78; for the reasons set forth in the Opinion being filed on even date; and for good cause shown;

IT IS on this 27th day of June, 2017,

ORDERED that Defendants' Motion to Dismiss is **GRANTED**, and Relator's Fourth Amended Complaint is **DISMISSED**.

/s/ Freda L. Wolfson
Hon. Freda L. Wolfson, U.S.D.J.