UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

UNITED STATES OF AMERICA, et al., ex rel. LESLEY FERRARA, et al., Plaintiffs, v. NOVO NORDISK, INC., et al., Defendants.	Civil Action Nos. 11-74 (RBW), 11-1596 (RBW), 11-1662 (RBW), 13-221 (RBW), 13-1529 (RBW), 17-791 (RBW)

AMENDED MEMORANDUM OPINION

The plaintiffs/relators brought the above-captioned cases on behalf of the United States and various plaintiff states (the "Named Plaintiff States") (collectively, the "government") against the defendants, Novo Nordisk, Inc. ("Novo Nordisk"), Novo A/S, Novo Nordisk A/S, and Novo Nordisk Foundation, pursuant to the qui tam provisions of the False Claims Act ("FCA"), 31 U.S.C. § 3730(b) (2012), and analogous state laws. See, e.g., Relator Elizabeth Kennedy's Original Complaint ¶¶ 5–8, United States ex rel. Kennedy v. Novo A/S, Civ. Action No. 13-1529 ("Kennedy's Compl.").[1] In July 2017, the United States, Novo Nordisk, and the relators entered into a settlement agreement resolving the relators' claims and requiring Novo Nordisk to pay to the United States and various states (the 'Medicaid Participating States') a total settlement amount of $46,500,000, plus interest (the "Total Settlement Amount"). See Relator Kennedy's Combined Reply Brief to Relators 4–6's Oppositions Regarding Relator Kennedy's

[1] Certain relators also brought claims on behalf of several cities. See, e.g., Kennedy's Compl. ¶ 162 (bringing claims on behalf of the City of Chicago). However, relator Kennedy's motion does not seek any proceeds related to such claims, see Relator Kennedy's Motion for Immediate Award of Relator's Share at 1 (seeking only a share "of the settlement amount that she is statutorily entitled to under the FCA and state statutes" (emphases added)), and thus, the Court need not address these claims at this time.

Status as First-to-File, Exhibit ("Ex.") B (Settlement Agreement) (the "Settlement Agreement") at 3–4. Currently before the Court is Relator [Elizabeth] Kennedy's Motion for Immediate Award of Relator's Share ("Kennedy's Mot."), which "seeks an immediate award of at least . . . [fifteen percent] of the settlement amount to which she is statutorily entitled [] under the FCA and state statutes," Kennedy's Mot. at 1. Upon consideration of the parties' submissions,[2] the Court concludes that it must grant in part and deny in part relator Kennedy's motion.

I. BACKGROUND

The relevant factual background is the following. "At all [ ] times [relevant to the Settlement Agreement], Novo Nordisk distributed, sold, and marketed pharmaceutical products throughout the United States, including the drug liraglutide with the trade name Victoza[.]" Settlement Agreement ¶ A. On January 25, 2010, "[t]he Food and Drug Administration ('FDA') approved a new drug application [ ] for . . . Victoza . . . as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus." Id. ¶ B. However,

[2] In addition to the filings already identified, the Court considered the following submissions in rendering its decision: (1) The Ferrara Relators' Memorandum in Support of Relator Kennedy's Motion for Immediate Award of Relator's Share ("Ferrara's Mem."); (2) Relator Peter Dastous'[s] Notice of Joinder in [ ] Relator Kennedy's 'Motion for Immediate Award of Relator's Share,' and [ ] Ferrara Relators' Memorandum in Support of Relator Kennedy's Motion ("Dastous's Not."); (3) The United States' Response to Relator Kennedy's Motion for Immediate Award of Relator Share ("United States' Resp."); (4) the Response of Named Plaintiff States to Motion of Kennedy for an Immediate Award of Relator Share ("Named Pl. States' Resp."); (5) Plaintiff/Relator David Myers'[s] Opposition to Relator Kennedy's Motion for Immediate Award of Relator's Share and Relator Ferrara's Memorandum in Support of Kennedy's Motion ("Myers's Opp'n"); (6) Plaintiff/Relator McKenzie Stepe's Opposition to Relator Kennedy's Motion for Immediate Award of Relator's Share and Relators Da[]sto[u]s and Ferrara's Memoranda in Support of Kennedy's Motion ("Stepe's Opp'n"); (7) Relators Kathleen Gratton and Raymond Hippolyte's Opposition to Relator Elizabeth Kennedy's Motion for Immediate Award of Relator's Share ("Gratton's Opp'n"); (8) Relator Kennedy's Combined Reply Brief to Relators 4-6's Oppositions Regarding Relator Kennedy's Status as First-to-File ("Kennedy's First-to-File Reply"); (9) Relator Kennedy's Reply Brief to United States' Response Regarding Relator's Share of Alternate Remedies ("Kennedy's Alternate Remedies Reply"); (10) the Ferrara Relators' Reply Brief to United States' Response (ECF 91) Regarding Relators' Share of Alternate Remedies ("Ferrara's Alternate Remedies Reply"); (11) the Ferrara Relators' Combined Reply Brief to Relators Myers, Stepe, and Gratton et al. (Relators 4-6) Oppositions Regarding Relator Kennedy's Status as First-to-File (ECF 96, Case No. 13-1529) ("Ferrara's First-to-File Reply"); (12) The United States' Response to the Oppositions of Relators Stepe, Myers, and Gratton and Hippolyte to Relator Kennedy's Motion for Immediate Award of Relator Share ("United States' 2d Resp."); and (13) Reply of Named Plaintiff States to Responses of Myers, Stepe[,] and Doe in Opposition to Motion of Kennedy for an Immediate Award of a Relator Share ("Named Pl. States' 2d Resp.").

> [a]t the time of approval and at all times since, Victoza's FDA-approved labeling has contained a boxed warning about the unknown risk of medullary thyroid carcinoma ('MTC') in humans, based on the fact that some rodents exposed to Victoza developed thyroid C-cell tumors . . . during premarket testing of the drug.

Id. ¶ C. Additionally, "[t]he FDA approved . . . Victoza with a Risk Evaluation and Mitigation Strategy ('REMS')," id. ¶ D, which required Novo Nordisk to, inter alia, "develop and implement a [ ] [p]lan . . . for communicating information to healthcare providers about the potential risk of MTC" (the "REMS Communication Plan"), id. ¶ E. The "REMS Communication Plan required Novo Nordisk to communicate this information in various forms, including in a letter to likely prescribers," id., and, on May 5, 2011, "the FDA . . . modifi[ed] [ ] the REMS[] to include an additional letter to primary care physicians," id. ¶ F.

Beginning on October 15, 2010, the relators filed their Complaints in this Court and various other district courts. See Kennedy's Compl. at 1 (filed Oct. 15, 2010); Complaint at 1, United States ex rel. Dastous v. Novo Nordisk, Inc., Civ. Action No. 11-1662 ("Dastous's Compl.") (filed Dec. 28, 2010); Complaint and Jury Demand at 1, United States ex rel. Ferrara v. Novo Nordisk, Inc., Civ. Action No. 11-74 ("Ferrara's Compl.") (filed Jan. 12, 2011); Complaint for False Claims Act Violations[,] 31 U.S.C. § 3729, Et Seq. at 1, United States ex rel. Myers v. Novo Nordisk, Inc., Civ. Action No. 11-1596 ("Myers's Compl.") (filed Sept. 2, 2011); Complaint Filed Under Seal Pursuant to 31 U.S.C. § 3730(b)(2) at 1, United States ex rel. Stepe v. Novo Nordisk, Inc., Civ. Action No. 13-221 ("Stepe's Compl.") (filed May 24, 2012); Complaint of the United States at 1, United States ex rel. Gratton v. Novo Nordisk, Inc., Civ.

Action No. 17-791 ("Gratton's Compl.") (filed Feb. 22, 2016).[3] Thereafter, all cases filed in other courts were transferred to this Court and assigned to the undersigned. See, e.g., Dkt. Entry, Kennedy, Civ. Action No. 13-1529, ECF No. 41 (reflecting transfer of case from the Southern District of Texas); Reassignment of Civil Case at 1, Kennedy, Civ. Action No. 13-1529 (reassigning case to the undersigned).

In July 2017, the United States, Novo Nordisk, and the relators entered into the Settlement Agreement, see generally Settlement Agreement at 18–21, which requires Novo Nordisk to pay the Total Settlement Amount to settle "certain civil claims [possessed by the government] against Novo Nordisk arising from [specific] conduct concerning the marketing, promotion, and sale of Victoza from January 1, 2010, through December 31, 2014" (the "Covered Conduct"), id. ¶ K. The Covered Conduct includes two categories of conduct. The first category includes the following alleged conduct:

> Novo Nordisk provided [its] sales force with training to appropriately implement the REMS, but also provided them with information that had the overall effect of arming them with messages that could create a false or misleading impression with physicians that the Victoza REMS MTC risk message was erroneous, irrelevant, or unimportant. Following the training, certain Novo Nordisk sales representatives made false or misleading statements that were designed to avoid and circumvent the requirements of the Victoza REMS Communication Plan. Those statements included:
>
> a. the potential risk of MTC associated with Victoza is only applicable to rats and mice;
>
> b. all diabetes drugs have boxed warnings and Victoza is no different and no less safe than those other drugs;
>
> c. because of differences between rodents and humans it is implausible that humans would contract MTC from the use of Victoza;

[3] A seventh set of relators filed a Complaint against Novo Nordisk on August 8, 2016. See Complaint at 1, United States ex rel. Smith v. Novo Nordisk, Inc., Civ. Action No. 16-1605. However, these relators stipulated to dismissal of their complaint without reserving a claim to a share of the relator's share to which she is statutorily entitled. See Stipulation of Dismissal at 3, Smith, Civ. Action No. 16-1605. Thus, this seventh Complaint is irrelevant to the Court's evaluation of relator Kennedy's motion for a share of the relator's share to which she is statutorily entitled.

d. physicians should not be concerned about MTC because it is easy to treat if a patient does get it;

e. "sandwiching" the MTC risk information between promotional messages; and

f. when delivering to primary care physicians a letter required by the May 5, 2011 modification to the Victoza REMS, certain Novo Nordisk sales representatives, executing instructions from Novo Nordisk's Vice President, Diabetes Marketing, told primary care physicians in June 2011 that there were no new safety concerns with Victoza and that the letter was simply the second part of the REMS requirement, which was a false or misleading message and contradicted the REMS modification[.]

Id. ¶ K(i). The Court will refer to this conduct as the "MTC Risk Conduct" and will refer to the government's claims based on this conduct as the "MTC Risk Conduct claims." The second category of Covered Conduct includes allegations that "Novo Nordisk knowingly promoted the sale to and use of Victoza by adult patients who did not have [t]ype [2] diabetes, a use for which it was not approved as safe and effective by the FDA, that was not a medically accepted indication . . . , and not covered by [ ] [f]ederal [h]ealth [c]are [p]rograms." Id. ¶ K(ii). The Court will refer to this conduct as the "Off-Label Promotion Conduct" and the government's claims based on this conduct as the "Off-Label Promotion Conduct claims."

The Settlement Agreement allocated $43,970,000 of the Total Settlement Amount to the MTC Risk Conduct (the "MTC Risk Settlement Amount") and the remaining $2,530,000 of the Total Settlement Amount to the Off-Label Promotion Conduct (the "Off-Label Promotion Settlement Amount"). Id. ¶ 6. Additionally, the Settlement Agreement instructed that Novo Nordisk would pay $43,179,036.87 of the Total Settlement Amount to the United States (the "Federal Settlement Amount"), id. ¶ 1(a), and $3,320,963.13 to the Medicaid Participating States (the " Medicaid Participating State Settlement Amount"), id. ¶ 1(b).

For purposes of "effectuating and formalizing" the Settlement Agreement, the United States partially intervened in the above-captioned cases "as to the Covered Conduct . . . , to the

extent that the [relators'] Complaint[s] contain[ed] such claims." See, e.g., The United States' Notice of Intervention in Part and Declination in Part at 1 (July 27, 2017), Kennedy, Civ. Action No. 13-1529. However, it "decline[d] intervention as to all other claims asserted on [its] behalf." Id. Shortly thereafter, the government and the relators stipulated to the "dismiss[al] with prejudice . . . [of] all claims asserted . . . against [Novo Nordisk] concerning the Covered Conduct," but agreed that the "[r]elator[s'] claims, if any, for a share of the [settlement] proceeds . . . [would] not be prejudiced until they are settled, adjudicated[,] or otherwise resolved." See, e.g., Stipulation of Dismissal at 1–2 (Aug. 2, 2017), Kennedy, Civ. Action No. 13-1529. Then, on September 5, 2017, the United States filed a new action against Novo Nordisk pursuant to the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 332 (2012), see Complaint ¶ 1, United States v. Novo Nordisk, Inc., Civ. Action No. 17-1820, which it stipulated to dismiss "pursuant to the settlement agreement the parties . . . entered into on July 26, 2017," Joint Stipulation for Dismissal and [Proposed] Order at 1 (Sept. 5, 2017), Novo Nordisk, Inc., Civ. Action No. 17-1820. "Novo Nordisk paid $12.15 million in connection with the FDCA [ ] settlement" (the "FDCA Settlement Amount"). United States' Resp. at 9.

On October 27, 2017, relator Kennedy filed her motion for an immediate award of a share of the Federal Settlement Amount and the portion of the Medicaid Participating State Settlement Amount paid to the Named Plaintiff States (the 'Named Plaintiff State Settlement Amount'). See Kennedy's Mot. at 1. Thereafter, relator David Myers, relator McKenzie Stepe, and relators Kathleen Gratton and Raymond Hippolyte (the "Gratton relators") filed oppositions to relator Kennedy's motion, also asserting entitlement to a share of the Federal Settlement Amount and Named Plaintiff State Settlement Amount. See Myers's Opp'n at 21; Stepe's Opp'n at 27; Gratton's Opp'n at 2–3. On the other hand, relators Lesley Ferrara and Shelly Kelling (the

"Ferrara relators") filed a memorandum supporting relator Kennedy's motion, see generally Ferrara's Mem., which relator Peter Dastous joined, see generally Dastous's Not. Additionally, relators Myers and Stepe each filed motions requesting that "the Court issue an Order [requiring the United States and the Named Plaintiff States] to deposit into . . . the Court's [r]egistry an amount . . . equal to [fifteen percent] of the [Federal Settlement Amount and Named Plaintiff State Settlement Amount]. . . pending the Court's resolution of the outstanding issues concerning the amount of the relator's share to be awarded to the various [r]elators." Plaintiff/Relator McKenzie Stepe's Motion to Deposit the Disputed Global Settlement Funds into the Court's Registry at 1, Stepe, Civ. Action No. 13-221; see Plaintiff/Relator David Myers's Motion to Deposit the Disputed Global Settlement Funds into the Court's Registry at 1, Myers, Civ. Action No. 11-1596. Then, the United States filed an unopposed motion similarly requesting that the Court order the deposit of fifteen percent of the Federal Settlement Amount into the Court's registry. See, e.g., United States' Unopposed Motion for Court Registry Deposit at 2–3, Kennedy, Civ. Action No. 13-1529.

On June 1, 2018, the Court granted the government leave to deposit fifteen percent of the Federal Settlement Amount and the Named Plaintiff State Settlement Amount into the Court's registry. See, e.g., Order at 3 (June 1, 2018), Kennedy, Civ. Action No. 13-1529, ECF No. 107. The Court further ordered that these amounts "be held in the Court's registry pending the Court's adjudication of the . . . dispute amongst the relators over entitlement to a relator share of the . . . settlement proceeds and until all appeals are exhausted (or the time for filing any notices of appeal has expired)." Id. This Memorandum Opinion constitutes the Court's adjudication of that dispute.

II. ANALYSIS

"The [FCA] broadly proscribes the knowing or reckless submission of false claims for payment to the federal government or within a federally funded program." United States ex rel. Heath v. AT&T, Inc., 791 F.3d 112, 115 (D.C. Cir. 2015) (internal citation omitted). The statute "allows a private person (a 'relator') to bring an action in the [g]overnment's name, and to recover a portion of the proceeds of the action, subject to the requirements of the statute." United ex rel. Batiste v. SLM Corp., 659 F.3d 1204, 1206 (D.C. Cir. 2011) (internal citations omitted) (citing 31 U.S.C. § 3730(b), (d)). Once a relator brings an action, "[t]he [g]overnment may elect to intervene and proceed with the action." 31 U.S.C. § 3730(b)(2). Regarding the portion of the proceeds that a relator may recover,

> [i]f the [g]overnment proceeds with an action brought by a . . . [relator], such [relator] shall[] . . . receive at least [fifteen] percent but not more than [twenty-five] percent of the proceeds of the action or settlement of the claim, depending upon the extent to which the [relator] substantially contributed to the prosecution of the action.

Id. § 3730(d)(1).[4] The various state statutes at issue in the above-captioned cases contain substantially similar provisions. See, e.g., Colo. Rev. Stat. § 25.5-4-306(4)(a)(I) (2018) ("If [a] state proceeds with an action brought by a relator . . . , the relator shall[] . . . receive at least fifteen percent but not more than twenty-five percent of the proceeds of the action or settlement of the claim, depending upon the extent to which the relator substantially contributed to the prosecution of the action.").

However, the FCA and state statutes place various limitations on the right of relators to recover part of the proceeds recovered in a case. Relevant here, § 3730(b)(5) provides: "When a

[4] The statute provides an exception to this rule for "action[s] . . . which the court finds to be based primarily on disclosures of specific [types of] information" that is publicly available, 31 U.S.C. § 3730(d)(1); however, the parties do not assert that this exception is applicable in this case, and thus, the Court need not address it.

[relator] brings an action . . . , no person other than the [g]overnment may intervene or bring a related action based on the facts underlying the pending action." 31 U.S.C. § 3730(b)(5). As this Circuit has explained,

> [o]nce a suit has been filed under the [FCA], the first-to-file rule prohibits any person, other than the government, from bring[ing] a related action based on the facts underlying the pending action. A second action is related, within the meaning of the first-to-file bar, if the claims incorporate the same material elements of fraud as the earlier action, even if the allegations incorporate additional or somewhat different facts or information. Similarity is assessed by comparing the complaints side-by-side and asking whether the later complaint alleges a fraudulent scheme the government already would be equipped to investigate based on [the first] [c]omplaint.

Heath, 791 F.3d at 121 (third, fourth, and fifth alterations in original) (internal quotation marks and citations omitted). In the context of a settlement, the first-to-file bar provides that "no qui tam plaintiff may . . . share in a government settlement if his or her allegations repeat claims in a previously filed action." United States ex rel. LaCorte v. SmithKline Beecham Clinical Labs., Inc., 149 F.3d 227, 230 (3d Cir. 1998); see United States ex rel. Dhillon v. Endo Pharm., 617 F. App'x 208, 212 (3d Cir. 2015) ("Only the first-filed [r]elator is entitled to a [r]elator's share award from a settlement.").[5]

Relator Kennedy, the first in time to file a complaint in the above-captioned cases, asserts that she is the only relator entitled to share in the Federal Settlement Amount and Named Plaintiff State Settlement Amount because she "was the first to allege and reveal the 'Covered Conduct.'" Kennedy's Mot. at 21. Specifically, she argues that "all other relators allege the

[5] Because the state false claims statutes at issue in this case have qui tam provisions nearly identical to the FCA's qui tam provisions, courts "have relied upon federal cases interpreting the FCA in construing the provisions of" these state statutes. See, e.g., City of Chi. ex rel. Rosenberg v. Redflex Traffic Sys., Inc., 884 F.3d 798, 802 (7th Cir. 2018) ("Given the substantive similarity between the Illinois False Claims Act (IFCA) and the FCA, Illinois courts have relied upon federal cases interpreting the FCA in construing the provisions of the IFCA." (internal citation omitted)). Thus, the Court's analysis of relator Kennedy's right to a share of the proceeds of the United States' settlement pursuant to the FCA applies equally to relator Kennedy's claim to a share of the proceeds of the State Settlement Amount pursuant to the state false claims statutes.

same material elements of fraud as . . . [her] [C]omplaint[] and are thus barred by the [f]irst-to-[f]ile rule." Id. at 26. Relator Dastous, the second-in-time filer, and the Ferrara relators, the third-in-time filers, support relator Kennedy's claim to the relator's share. See Ferrara's Mem. ¶ 1 ("The Ferrara [r]elators support the award of [the] relator's share to [r]elator Kennedy and submit that only [r]elator Kennedy, or, in the alternative, the Ferrara [r]elators[,] qualify as 'first-to-file' under the federal[] [and] state[] . . . qui tam statutes."); Dastous's Not. at 3 (asserting that relator Dastous "joins in" relator Kennedy's motion and the Ferrara relators' memorandum in support of relator Kennedy's motion).[6]

However, relator Myers, the fourth filer, relator Stepe, the fifth filer, and the Gratton relators, the sixth filers (the "objecting relators"), oppose relator Kennedy's claim. They argue that relator Kennedy is not entitled to share in the MTC Risk Settlement Amount because "[n]othing in . . . [her] Complaint would have alerted the [g]overnment to the REMS scheme." Myers's Opp'n at 18; see Stepe's Opp'n at 24 (same); Gratton's Opp'n at 15 (same). Rather, they argue that "it was [r]elator Dastous[] who[] . . . first alleged the facts forming the basis of Novo[] Nordisk['s] scheme to minimize and mischaracterize Victoza's black box warning." Myers's Opp'n at 19; see Stepe's Opp'n at 25 (same); Gratton's Opp'n at 15 ("Relator Dastous's [C]omplaint[] . . . alleges the very wrongdoing that forms the basis of the REMS scheme that the [g]overnment settled with Novo Nordisk."). They further argue that "general principles of equity require that [their] extensive contributions to the government's global settlement entitle [them] to receive a portion of the settlement funds." Myers's Opp'n at 21 (capitalization removed); see Stepe's Opp'n at 27 (same); Gratton's Opp'n at 16 ("Equity [r]equires [t]hat [a]ll of the [r]elators

[6] Because relator Dastous did not insert page numbers on his Notice, the page numbers cited by the Court when referencing this filing are the automatically-generated page numbers assigned by the Court's Case Management/Electronic Case Filing system.

[w]ho [c]ontributed to the [g]lobal [s]ettlement [r]eceive a [r]elator's [s]hare of the [Federal Settlement Amount and Named Plaintiff State Settlement Amount]."). [7] Finally, the Gratton relators argue that "[a] full evidentiary hearing, with testimony from the [g]overnment as to the value of the contributions that each particular relator brought to the global settlement . . . , is required" to determine which relators are entitled to a share. Gratton's Opp'n at 19.

The government "takes no position regarding which relator, if any, is entitled to the relator share for the two categories of claims that are part of the . . . [S]ettlement [Agreement]." United States' Resp. at 2; see Named Pl. States' Resp. at 2 (same). However, the government argues that "the Court may not make an 'equitable award' to a relator who is barred" by the first-to-file rule, and "that an evidentiary hearing is neither needed nor proper to resolve the first-to-file issue." United States' 2d Resp. at 2; see Named Pl. States' 2d Resp. at 2 (incorporating the United States' arguments). The Court will address the relators' arguments as to each category of Covered Conduct separately.

A. The MTC Risk Settlement Amount

Relator Kennedy argues that she is the sole relator entitled to share in the MTC Risk Settlement Amount because she "was the first to alert the [g]overnment [to] Novo Nordisk's concerted, nationwide scheme to downplay and misrepresent Victoza's potential risk of . . . []MTC[,]" and thus, all other relators are barred from recovering a share. Kennedy's Mot. at 15. She further argues that it is irrelevant that she "did not frame [Novo Nordisk's] fraudulent conduct as REMS violations" because (1) "the [f]irst-to-[f]ile rule does not contemplate providing allegations of a legal theory, but of the 'material elements of fraud'—that is to say, of

[7] Significant portions of the analysis contained in the oppositions filed by relator Myers, relator Stepe, and the Gratton relators are substantially similar and, in some cases, identical. Compare, e.g., Myers's Opp'n at 13–18, with Stepe's Opp'n at 19–24. Thus, when citing to these portions later in this Memorandum Opinion, the Court will only cite to relator Myers's opposition to avoid repetitive citations.

the facts of the fraud"; (2) her "factual allegations regarding Novo Nordisk's fraudulent conduct[] . . . constitute violations of the Victoza REMS"; and (3) her "allegations put the [g]overnment on the trail of the fraud of the other marketing strategies Novo Nordisk employed to downplay Victoza's safety risks." Id. at 21. The Ferrara relators, in support of relator Kennedy's motion, assert that "[t]he allegations by [r]elator Kennedy involve the same drug, the same marketing scheme[,] and include many of the facts detailed in the Covered Conduct." Ferrara's Mem. at 5. The objecting relators respond that relator Kennedy is not entitled to share in the MTC Risk Settlement Amount because "the scheme described in [her] Complaint is not the same scheme—neither in type of wrongdoing nor geographic scope—that is detailed in the [ ] Settlement Agreeement." See, e.g., Myers's Opp'n at 13. Specifically, they argue that "[t]he [ ] Settlement Agreement details a discrete and specific scheme in which Novo [Nordisk], at a national level, attempted to undermine the FDA's REMS," while "[t]he Kennedy Complaint details a scheme in which Novo [Nordisk] improperly marketed Victoza for off-label use in the Gulf Coast area" and "is devoid of any mention of the REMS." See, e.g., id.

As already explained, the FCA and the relevant state statutes provide that, "[i]f the [g]overnment proceeds with an action brought by a [qui tam relator] . . . , such person shall . . . receive at least [fifteen] percent but not more than [twenty-five] percent of the proceeds of the action or settlement of the claim." 31 U.S.C. § 3730(d)(1). As an initial matter, the parties appear to agree that the government's intervention in relator Kennedy's case is not sufficient to demonstrate that she is per se entitled to share in the proceeds of the government's settlement of her case. Rather, they assume that relator Kennedy must demonstrate a link between the claims settled by the government and the claims raised in her complaint. See, e.g., Kennedy's Mot. at 21 (arguing that relator Kennedy is entitled to share in the MTC Risk Settlement Amount

because "she . . . allege[d] and reveal[ed] the 'Covered Conduct'"); Myers's Opp'n at 13 (arguing that relator Kennedy is not entitled to share in the MTC Risk Settlement Amount because "the scheme described in [her] Complaint is not the same scheme[] . . . that is detailed in the [ ] Settlement Agreement"). Although this Circuit has not addressed this issue, the Eighth Circuit has concluded that a "relator['s] right to recovery [under § 3730(d)(1)] is limited to a share of the settlement of the claim that [he or she] brought" and "does not extend to a different claim that is settled by the government when that claim was not originally 'brought by' the relator." Rille v. PricewaterhouseCoopers LLP, 803 F.3d 368, 372 (8th Cir. 2015). The Eighth Circuit reasoned that "§ 3730(d)(1) is clear that the relator's share [of a settlement] is based only on proceeds of 'the claim[,]' . . . [which] refers back to the claim that is 'brought by' the relator in 'an action' that [he or s]he initiates." Id. The Court agrees with this interpretation of § 3730(d)(1) and, thus, agrees with the parties that relator Kennedy must demonstrate that she originally "brought" the government's MTC Risk Conduct claims.

The question for the Court is therefore whether relator Kennedy's claims are the same as or different from the MTC Risk Conduct claims for purposes of § 3730(d)(1). The parties appear to assume that the appropriate test for determining this issue is this Circuit's test for determining whether two claims are "related" for purposes of the first-to-file bar set forth in § 3730(b)(5). See, e.g., Kennedy's Mot. at 22 (arguing that she is entitled to a share because she was the first to allege "the [m]aterial [e]lements of [f]raud" underlying the Covered Conduct). As already explained, § 3730(b)(5) provides that "[w]hen a [relator] brings an action . . . , no person other than the [g]overnment may intervene or bring a related action based on the facts underlying the pending action." 31 U.S.C. § 3730(b)(5). And, this Circuit has concluded that an action is "related" to a pending action if it "incorporate[s] the same material elements of fraud" as the

pending action, instructing that "[s]imilarity is assessed by comparing the complaints side-by-side and asking whether the later complaint alleges a fraudulent scheme the government already would be equipped to investigate based on [the first] [c]omplaint." Heath, 791 F.3d at 121 (alterations in original) (internal quotation marks and citations omitted).

The Court agrees with the parties that the test for determining whether an action is "related" for purposes of § 3730(b)(5)'s first-to-file bar is appropriate for determining whether relator Kennedy's claims are the same claims settled by the government for purposes of § 3730(d)(1). As this Circuit has observed, all of the qui tam provisions arising out of "[t]he 1986 amendments [to the FCA] . . . must be analyzed in the context of the[] twin goals of rejecting suits which the government is capable of pursuing itself, while promoting those which the government is not equipped to bring on its own." United States ex rel. Hampton v. Columbia/HCA Healthcare Corp., 318 F.3d 214, 217 (D.C. Cir. 2003) (second alteration in original) (quoting United States ex rel. Springfield Terminal Ry. Co. v. Quinn, 14 F.3d 645, 651 (D.C. Cir. 1994)). Based on these goals, the Circuit has interpreted § 3730(b)(5) to allow recovery by a first-filed relator, and preclude recovery by subsequent relators, when the first-filed relator's complaint alleges the "material elements of fraud" at issue and "equip[s] the government to investigate" that fraud. Batiste, 659 F.3d at 1209; see id. at 1210 (observing that § 3730(b)(5) "allow[s] recovery when a qui tam relator puts the government on notice of potential fraud being worked against the government"). Because § 3730(d)(1) shares these same goals,[8] the Court finds it appropriate to interpret § 3730(d)(1) to also allow recovery when this

[8] Section 3730(d)(1) is a product of the 1986 amendments to the FCA. Prior to these amendments, the FCA provided in § 3730(c)(1) that, "[i]f the [g]overnment proceeds with an action, the . . . [relator] may receive an amount the court decides is reasonable . . . [, which] may not be more than [ten] percent of the proceeds of the action or settlement of a claim." 31 U.S.C. § 3730(c)(1) (1982); see United States ex rel. Alderson v. Quorum Health Grp., Inc., 171 F. Supp. 2d 1323, 1331 (M.D. Fla. 2001) (recognizing that prior to the 1986 amendments, "the relator's award in the 'standard' qui tam action was capped at ten percent of the recovery"). By adding § 3730(d)(1), the (continued . . .)

same test is satisfied. See Hampton, 318 F.3d at 217 (adopting this Circuit's "material elements" test for § 3730(e)(4)(A) in the context of § 3730(b)(5)'s first-to-file bar because, although "[t]he language of § 3730(b)(5) differs from that of § 3730(e)(4)(A), [ ] the objectives of § 3730(b)(5)—encouraging whistle-blowing and discouraging opportunistic behavior—are the same").[9] Accordingly, the Court concludes that § 3730(d)(1) permits a relator to recover the proceeds of a government settlement if the relator demonstrates that her complaint "incorporate[s] the same material elements of fraud" as the claim settled by the government, such that it "equipped the government to investigate" that fraud. Heath, 791 F.3d at 121.

Applying this test here, the Court finds that relator Kennedy alleged "the same material elements of fraud" as the government alleged as the basis for the MTC Risk Conduct claims. Id. As this Circuit instructed in Hampton, the "material elements" of a typical claim under the FCA are that "the defendant presented . . . a claim to the government, that the claim was false, and that the defendant knew that the claim was false." 318 F.3d at 218. Here, both relator Kennedy's Complaint and the Settlement Agreement allege that Novo Nordisk caused claims for Victoza to

(. . . continued)
1986 amendments increased the relator's award in a case in which the government has intervened to a minimum of fifteen percent and a maximum of twenty-five percent. See False Claims Amendments Act of 1986, Pub. L. No. 99-562, § 3, 100 Stat. 3153, 3156 (Oct. 27, 1986) (codified at 31 U.S.C. § 3730(d)(1)).

[9] The Court acknowledges that a handful of courts, including another member of this Court, have adopted a slightly different test. Specifically, they have concluded that a relator's claims are the same as the government's settled claims when "the conduct contemplated in the settlement agreement . . . overlap[s] with the conduct alleged in [the] [r]elator's complaint." Rille, 803 F.3d at 373–74 (first, second, and third alterations in original) (quoting United States ex rel. Bledsoe v. Cmty. Health Sys., Inc. (Bledsoe I), 342 F.3d 634, 651 (6th Cir. 2003)); see United States ex rel. Shea v. Verizon Commc'ns, Inc., 844 F. Supp. 2d 78, 92 (D.D.C. 2012) (concluding that "there must be some findings of [factual] overlap between the qui tam claims and the [g]overnment claims before a [ ] [r]elator has a right to recover a share of the [g]overnment's [settlement] proceeds" (first alteration in original) (quoting Bledsoe I, 342 F.3d at 651)). However, the Court declines to adopt this "factual overlap" test because its parameters are unclear, i.e., it is unclear to what extent the conduct asserted in the settlement agreement must "overlap" with the conduct alleged in the complaint. In any event, the "factual overlap" test is consistent with this Circuit's "material elements of fraud" test, as both tests emphasize the facts underlying the claims being compared and do not require the claims being compared to be identical. Compare Rille, 803 F.3d at 374 (requiring only "a factual overlap for the relators to recover" pursuant to § 3730(d)(1)), with Heath, 791 F.3d at 116 (analyzing whether two actions were "related" in terms of whether they "target[ed] factually distinct types of frauds" (emphasis added)), and Hampton, 318 F.3d at 217 ("reject[ing] . . . [a] test[] [ ] barring claims based on 'identical facts'").

be submitted to government healthcare programs, see, e.g., Kennedy's Compl. ¶ 168 (alleging that "Novo Nordisk[] . . . cause[d] false claims [for Victoza] to be submitted by physicians and pharmacists [to state and federal healthcare programs] in violation of the FCA"); Settlement Agreement ¶ K ("alleg[ing] that Novo Nordisk caused false or fraudulent claims for Victoza to be submitted to, or caused purchases by, [ ] [f]ederal [h]ealth [c]are [p]rograms"); that the claims were false because Novo Nordisk marketed Victoza in a manner that misled physicians about the risk of MTC, see, e.g., Kennedy's Compl. ¶ 77 (alleging that Novo Nordisk's "false claims" included "committ[ing] to a marketing campaign that . . . downplay[ed] and thus misrepresent[ed] the risks of thyroid cancer . . . as spelled out on Victoza's label"); Settlement Agreement ¶ K(i) (alleging, inter alia, that Novo Nordisk "provided [its sales force] with information that had the overall effect of arming them with messages that could create a false or misleading impression with physicians that the Victoza REMS MTC risk message was erroneous, irrelevant, or unimportant"); and that Novo Nordisk knew that these claims were false, see Kennedy's Compl. ¶ 178 (alleging that "Novo Nordisk knowingly caused [ ] false or fraudulent claims [for Victoza] to be presented for payment or approval"); cf. Settlement Agreement ¶ K(i) (although not explicitly alleging Novo Nordisk's knowledge, implying knowledge by alleging that "Novo Nordisk . . . provided [its sales force] with information that had the overall effect of arming them with messages that could create a false or misleading impression with physicians that the Victoza REMS MTC risk message was erroneous, irrelevant, or unimportant"). Moreover, with respect to Novo Nordisk's allegedly misleading marketing scheme, both relator Kennedy's Complaint and the Settlement Agreement allege that Novo Nordisk representatives made statements that gave physicians the false or misleading impression that the MTC risk associated with Victoza was not a concern, see Kennedy's Compl. ¶ 139

(alleging examples of such misrepresentations, including statements that Victoza's MTC risk was "not concerning" and that there were "no thyroid ca[ncer] problems"); Settlement Agreement ¶ K(i) (alleging that "certain Novo Nordisk sales representatives made false or misleading statements" regarding Victoza's MTC risk, such as that "the potential risk of MTC associated with Victoza is only applicable to rats and mice"), and that Novo Nordisk trained its sales representatives to make such statements, see Kennedy's Compl. ¶ 1 (alleging that Novo Nordisk "trained its sales force to make . . . these assertions"); Settlement Agreement ¶ K(i) (alleging that "Novo Nordisk provided the sales force . . . with information that had the overall effect of arming them with messages that could create a false or misleading impression with physicians that the Victoza REMS MTC risk message was erroneous, irrelevant, or unimportant"). Thus, relator Kennedy's Complaint and the Settlement Agreement "allege essentially the same corporation-wide scheme" and, accordingly, relator Kennedy's Complaint "suffice[d] to equip the government to investigate" the fraudulent scheme alleged in the Settlement Agreement. Batiste, 659 F.3d at 1209 (concluding that a subsequent complaint alleged the same fraudulent scheme as a first-filed complaint where the two relators "broadly allege[d] that the same fraudulent activities occurred at each of their offices, for the same reasons, and that similar [ ] corporate policies promoted the fraudulent behavior").

The objecting relators' counterarguments are unpersuasive. They first argue that the Kennedy Complaint did not allege the same "type of wrongdoing" as the Settlement Agreement because it "is devoid of any mention of the REMS." See, e.g., Myers's Opp'n at 13. However, the objecting relators appear to concede that relator Kennedy need not specifically reference the REMS to share in the MTC Risk Settlement Amount, as they argue that relator Dastous, whose Complaint also failed to mention the REMS, see generally Dastous's Compl., is the relator

entitled to recover the relator's share of that Amount, see, e.g., Myers's Opp'n at 20–21. In any event, the Court cannot agree that relator Kennedy's failure to reference the REMS makes the fraud she alleges "factually distinct" from the fraud alleged in the Settlement Agreement. Id. at 16 (quoting Heath, 791 F.3d at 121). Although the Settlement Agreement asserts that the MTC Risk Conduct was "designed to avoid and circumvent the requirements of the Victoza REMS Communication Plan," Settlement Agreement ¶ K(i), and relator Kennedy asserted that it constituted off-label marketing, see, e.g., Kennedy's Compl. ¶¶ 1, 23–25, both positions appear to be means of demonstrating that Novo Nordisk's marketing of Victoza violated the FDCA, and thus, the claims for reimbursement that it submitted to government healthcare programs for Victoza were legally "false," id. ¶ 23 (explaining that "[w]hen a company markets a drug off-label, the drug . . . is considered 'misbranded'" in violation of the FDCA); see 21 U.S.C. § 352(y) (instructing that a drug is "misbranded" "[i]f it is . . . subject to an approved [REMS] . . . and the responsible person . . . fails to comply with a requirement of such [REMS]"); United States ex rel. Campie v. Gilead Scis., Inc., No. C-11-0941 EMC, 2015 WL 106255, at *7, *11–13 (N.D. Cal. Jan. 7, 2015) (addressing, but ultimately rejecting, a relator's theory that "reimbursement claims . . . were legally false in that they were tainted by some underlying statutory, regulatory, or contractual violation made in connection with [those] claim[s], which renders the claim[s] ineligible for reimbursement" (second, third, and fourth alterations in original) (internal quotation marks and citation omitted)). However, the question the Court must answer is not whether relator Kennedy alleged the specific legal theory that the government ultimately found persuasive, but whether relator Kennedy's allegations sufficed to equip the government to investigate the fraudulent scheme alleged in the Settlement Agreement. See United States v. Unisys Corp., 178 F. Supp. 3d 358, 369 (E.D. Va. 2016) (recognizing in the

first-to-file bar context that "the focus must be on the commonality of the facts" and not the "legal theory" of the fraud).

Relator Kennedy's Complaint not only equipped the government to investigate the fraudulent scheme underlying the MTC Risk Conduct claims for the reasons already explained, it also equipped the government to develop its theory that Novo Nordisk's misrepresentations about the risk of MTC "were designed to avoid and circumvent the requirements of the Victoza REMS Communication Plan." Settlement Agreement ¶ K(i); see Batiste, 659 F.3d at 1209. A government investigator researching Victoza's warning label regarding MTC risk would have easily found the Victoza REMS, which is publicly available. See generally Risk Evaluation and Mitigation Strategy (REMS), https://www.fda.gov/downloads/drugs/drugsafety/postmarketdrugsafetyinformationforpatientsandproviders/ucm202063.pdf (last visited Mar. 11, 2019). Thus, considering that the stated goal of the REMS is to "inform[] healthcare providers about the potential risk of [MTC] . . . associated with VICTOZA®," id. at 1, the REMS would have put the government on notice that the conduct alleged by relator Kennedy may have been designed to circumvent the REMS. Additionally, the government's knowledge that Novo Nordisk may have been working to undermine the stated goal of the REMS would have put the government on notice that Novo Nordisk also may have violated specific requirements of the REMS. See Settlement Agreement ¶ K(i)(f) (providing as an example that sales representatives misrepresented the purpose of "a letter required by the May 5, 2011 modification to the Victoza REMS"). Thus, relator Kennedy's allegations that Novo Nordisk misrepresented Victoza's MTC Risk sufficed to equip the government to discover the alleged motive behind and legal implications of that conduct. See United States ex rel. Folliard v. CDW Tech. Servs., Inc., 722 F. Supp. 2d 37, 43 (D.D.C. 2010) (concluding that a first-filed complaint alleging fraud by the

defendant regarding certain federal procurement contracts governed by the Trade Agreements Act ("TAA") sufficed to equip the government to investigate potential fraud in other TAA contracts because the government "could have easily reviewed publicly available information to determine whether [the defendant] was a party to other government procurement contracts that required TAA-compliance").

Moreover, concluding that relator Kennedy's failure to characterize the MTC Risk Conduct as a violation of the REMS bars her from recovering would frustrate the purposes of the FCA. Specifically, it would permit "the government [to] deprive [a] relator of h[er] right to recover simply by recasting the same or similar factual allegations in a new claim," Rille, 803 F.3d at 374, which would frustrate the FCA's purpose of "promoting [suits] which the government is not equipped to bring on its own," Springfield Terminal Ry. Co., 14 F.3d at 651. Thus, the Court concludes that relator Kennedy's failure to characterize her allegations as efforts to circumvent the REMS does not defeat her claim to a share of the MTC Risk Settlement Amount.

The Court must also reject the objecting relators' argument that relator Kennedy's recovery is defeated by her "failure to mention . . . any [of the] misrepresentations that were included in the [ ] Settlement Agreement," see, e.g., Myers's Opp'n at 16, and by her failure to allege the "active misrepresentations" that were the Settlement Agreement's focus, id. at 15. Although relator Kennedy's Complaint does not allege the specific examples of misrepresentations included in the Settlement Agreement,[10] she did broadly allege that Novo

[10] Relator Kennedy attempts to demonstrate that she alleged specific examples of misrepresentations provided in the Settlement Agreement by pointing to a statement appearing in the exhibit submitted with her Complaint, see Kennedy's Mot. at 20 (pointing to a statement by a doctor contained on page 57 of the exhibit to demonstrate that she alleged "that Novo Nordisk sales representatives downplayed Victoza's black box warning by pointing out that all competitor drugs have a black box warning"), and by citing a document referenced in her Complaint, but not attached to it, see id. at 16 (referencing a "Victoza Launch Roadmap"). However, because this evidence was either

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Nordisk "misrepresent[ed] the risks of [MTC] . . . as spelled out on Victoza's label," Kennedy's Compl. ¶ 77, and provided examples of substantially similar misrepresentations, see, e.g., id. ¶ 139 (alleging that Novo Nordisk representatives told physicians that MTC was "not a concern" and "there[] [is] no increase[d] incidence of thyroid cancer in humans"). Thus, the misrepresentations alleged in the Settlement Agreement are "merely variations" of the fraudulent scheme and misrepresentations alleged in relator Kennedy's Complaint. Hampton, 318 F.3d at 219; see id. (concluding that a first-filed complaint "broad[ly] alleg[ing]" "fraud in providing home health care services through numerous subsidiaries" barred a second-filed complaint alleging such fraud at a subsidiary not mentioned in the first complaint); see Foillard, 722 F. Supp. 2d at 41 (barring a second-filed "complaint [that] merely allege[d] a variation on how [the defendant] defrauded the government"). And, relator Kennedy's allegations regarding Novo Nordisk's alleged scheme to misrepresent the risk of MTC and the examples of its misrepresentations sufficed to equip the government to discover the additional examples of misrepresentations or means of accomplishing the scheme that are identified in the Settlement Agreement. See Batiste, 659 F.3d at 1209 (concluding that a relator's allegations that the defendant company falsified forbearances, primarily by "fabricati[ng] [ ] oral forbearance requests," sufficed to "give the government grounds to investigate" allegations in a subsequent complaint regarding "the offering of forbearances to unqualified borrowers"). Moreover, the objecting relators' argument that relator Kennedy's allegations failed to notify the government of the "active misrepresentations" at issue in the Settlement Agreement, see, e.g., Myers's Opp'n at

(. . . continued)
buried in her exhibit, see Kennedy's Compl., Ex. 1 (Impact RX Reports) at 57, or not provided in her Complaint, the Court finds it difficult to conclude that relator Kennedy put the government on notice of these specific statements and their relevance to the fraudulent scheme she alleged. In any event, for the reasons explained above, the allegations appearing in the numbered paragraphs of relator Kennedy's Complaint sufficed to put the government on notice of the fraud underlying the MTC Risk Conduct claims, and thus, the Court need not analyze the significance of these statements, because they have no impact on the Court's analysis.

15, is not only immaterial for the reasons already discussed, but overlooks the affirmative misrepresentations alleged by relator Kennedy, see, e.g., Kennedy's Compl. ¶ 139 (alleging that Novo Nordisk representatives told physicians that MTC was "not a concern" and "there[] [is] no increase[d] incidence of thyroid cancer in humans"). Thus, the objecting relators' argument that relator Kennedy cannot share in the MTC Risk Settlement Amount because she failed to allege the same, or same type of, misrepresentations alleged by the Settlement Agreement also fails.[11]

Additionally, the Court must reject the objecting relators' argument that the fraudulent schemes alleged in the Settlement Agreement and in relator Kennedy's Complaint do "not [have] the same . . . geographic scope" because the Complaint focuses on "individuals associated with Novo[] [Nordisk's] Mobile, Alabama office" and "the Gulf Coast area." See, e.g., Myers's Opp'n at 13. Although certain of relator Kennedy's allegations concern Novo Nordisk employees in Mobile or the Gulf Coast region, see, e.g., Kennedy's Compl. ¶ 120 (referring to conduct by a "Dallas District Business Manager" and a "Regional Business Director" and describing its effects on "her Mobile West territory"), she also alleged that Novo Nordisk's illegitimate promotion of Victoza was a "nationwide scheme," id. ¶ 3; see, e.g., id. ¶ 80 (alleging that "Novo Nordisk's management participated in the off-label marketing scheme or knew of it

[11] The objecting relators also argue that the misrepresentations alleged by relator Kennedy "were not enough to alert the [g]overnment to the scheme detailed in the [ ] Settlement Agreement" because they are drawn from "randomly excerpted notes from unknown individuals, without context." See, e.g., Myers's Opp'n at 16. However, the statements cited by relator Kennedy in her Complaint are not "without context," but are excerpted from an exhibit attached to her Complaint that she represents contains "market research reports circulated to the sales force, including verbatim notes from interviews with doctors after meeting with Novo Nordisk sales representatives" regarding Victoza. Kennedy's Compl. ¶ 2; see, e.g., id., Ex. 1 (Impact RX Reports) at 14 (reflecting alleged statement that "black box warning not concerning"). In any event, at this stage of this litigation, the Court need only determine whether relator Kennedy's allegations "put[] the government on notice of potential fraud being worked against the government." Batiste, 659 F.3d at 1210. It need not consider the value of the evidence she offered to support her allegations, which is relevant only to the Court's determination of the amount of the settlement funds relator Kennedy is entitled to receive. See Shea, 844 F. Supp. 2d at 81–82 (explaining that "the [ ] factors a court should consider in determining the relator's share[] [include] the significance of the information provided by the relator, the relator's contribution to the final outcome, and whether the [g]overnment previously knew such information").

yet did nothing to limit it," including its "Vice President [of] National Diabetes Sales," "Chief Compliance Officer," and "Chief Medical Officer"). Notably, relator Kennedy alleged that the misrepresentations regarding MTC risk that she cited in her Complaint were drawn from "nationwide" marketing reports. See id. ¶ 99 (alleging that these reports "confirm[ed] that sales representatives nationwide were receiving the same directives to market off-label that her district was receiving"); see also id., Ex. 1 (Impact RX Reports) at 6 (report titled "US Weekly Launch Tracker"). Moreover, like the Settlement Agreement, many of relator Kennedy's allegations are directed at Novo Nordisk as a whole, rather than specific members or components of its sales force. See, e.g., id. ¶ 1 (alleging that "Novo Nordisk trained its sales force to make . . . [fraudulent] assertions" regarding Victoza, including assertions "downplaying [Victoza's] safety issues and side effects" (emphasis added)). Thus, relator Kennedy's references to local events do not defeat her allegations of a broader nationwide scheme. See Batiste, 659 F.3d at 1209 (concluding that a relator alleged a "nationwide scheme" against the defendant despite "focus[ing] on activities at a[] [subsidiary's] office in New Jersey where he worked").

Finally, the cases cited by the objecting relators are distinguishable. In Heath, this Circuit compared a complaint alleging a scheme by employees of an AT & T subsidiary to overcharge Wisconsin schools eligible for discounted services under the federal E-Rate program with a second complaint alleging "a nationwide scheme centered in AT & T's corporate headquarters of mischarging the E-Rate program" "through institutionalized disregard of the . . . [program] requirement[s] [ ] in [its] employee-training and billing procedures." 791 F.3d at 121–22. In concluding that the "two complaints target[ed] factually distinct types of frauds," the Circuit reasoned that "[n]othing in the [first] complaint would have alerted the United States government to [the] nationwide scheme" alleged in the second complaint, id. at 121, as the first

"complaint disclose[d] nothing more than the rogue actions of individuals within a single AT & T subsidiary and their specific, overt misrepresentations," id. at 121–22, and "did not allege that AT & T encouraged [the subsidiary's] fraud or affirmative misrepresentations, or even knew anything about them," id. at 122. Here, by contrast, relator Kennedy alleged that employees' misrepresentations regarding Victoza's MTC risk were part of a "nationwide scheme," Kennedy's Compl. ¶ 3, and that Novo Nordisk "trained its sales force to make . . . these assertions," id. ¶ 1. Thus, Heath does not change this Court's conclusion that the fraudulent scheme alleged by relator Kennedy "put the government on notice of both the nature and reach of the [ ] fraud" alleged in the Settlement Agreement. Heath, 791 F.3d at 122.

The Ninth Circuit's decision in United States ex rel. Hartpence v. Kinetic Concepts, Inc., 792 F.3d 1121 (9th Cir. 2015), and the Eastern District of Pennsylvania's decision in United States ex rel. Galmines v. Novartis Pharms. Corp., Civ. Action No. 06-3213, 2013 WL 2649704 (E.D. Pa. June 13, 2013), are also distinguishable. In Hartpence, the Ninth Circuit concluded that two alleged frauds were "materially different" because they "existed completely independent of one another": one involved allegations that the defendant caused the government to "pay[] for [medical] devices that were never used" by submitting claims for the devices before receiving written orders from physicians, while the other involved allegations that the defendant caused the government to "pay[] for [medical] devices which were used, but unnecessary for treatment" by misusing a claims coding system. 792 F.3d at 1131. Here, the fraud alleged by relator Kennedy is based on the same type of conduct as the MTC Risk Conduct alleged in the Settlement Agreement, namely, a scheme by Novo Nordisk to mislead physicians regarding Victoza's MTC risk, and thus, this Court cannot conclude that these frauds "existed completely independent of one another." Id. Moreover, in Galmines, the Eastern District of Pennsylvania compared two

off-label promotion schemes involving a drug approved as a second-line treatment for atopic dermatitis, specifically, a scheme to promote the drug for the treatment of psoriasis and seborrhea and a scheme to promote the drug for infant use and as a first-line treatment for atopic dermatitis. 2013 WL 2649704, at *1, *10. The court concluded that the two schemes were "different" because "[n]o reasonable reading" of the allegations supporting the first scheme "would have informed the government of the need to investigate" the second. Id. at *10. However, this Court has determined for the reasons already explained that relator Kennedy's allegations sufficed to put the government on notice of the MTC Risk Conduct alleged in the Settlement Agreement. Thus, neither Hartpence nor Galmines undermines the Court's conclusion that the fraud alleged by relator Kennedy is the same as the fraud alleged in the Settlement Agreement for purposes of § 3730(d)(1).

In sum, the Court concludes that relator Kennedy is entitled to a relator's share of the MTC Risk Settlement Amount pursuant to § 3730(d)(1). However, this conclusion does not end the Court's inquiry. The Court must next evaluate relator Kennedy's claim that her Complaint bars the other relators in this case from also sharing in the MTC Risk Settlement Amount. As an initial matter, the Court rejects the Gratton relators' position that "[a] full evidentiary hearing[] . . . is required" to determine whether the first-to-file rule bars any of the relators in this case from sharing in the MTC Risk Settlement Amount. Gratton's Opp'n at 19. As this Circuit has instructed, resolving the first-to-file issue requires only that the Court "compar[e] the complaints side-by-side," Heath, 791 F.3d at 121, and thus, additional evidence is unnecessary to this assessment, see United States ex rel. Ortega v. Columbia Healthcare, Inc., 240 F. Supp. 2d 8, 15 (D.D.C. 2003) (rejecting a relator's request for an evidentiary hearing regarding the FCA's first-to-file bar because "[t]he only evidence needed to determine if a complaint is barred by

§ 3730's first-to-file rule is the complaints themselves"); see also LaCorte, 149 F.3d at 234 n.6 (rejecting a relator's request to "remand his claims to the district court for discovery" on a first-to-file issue because a court "may decide whether [ ] later complaints allege the same material elements as claims in the original lawsuits simply by comparing the original and later complaints, [and thus,] further factual development is unnecessary").

Upon consideration of the relators' Complaints in the above-captioned cases, the Court concludes that no relator other than relator Kennedy is entitled to share in the MTC Risk Settlement Amount. Although the objecting relators argue that relator Dastous, the second-filed relator, "facially allege[d] the very wrongdoing that forms the basis of the REMS scheme that the [g]overment settled with Novo [Nordisk]," Myers's Opp'n at 20, the Court cannot locate any such allegations in relator Dastous's Complaint. Rather, relator Dastous's Complaint almost exclusively focuses on Novo Nordisk's alleged off-label promotion of Victoza for weight loss and, although it references Victoza's MTC risk, it appears to do so only to demonstrate that such off-label "promotion . . . imperils patient health." Dastous's Compl. ¶ 4 ("Over and above the inherent risks of using a drug in a manner for which it has not been approved, Victoza also carries serious risks."); see id. ¶¶ 56–58 (describing and quoting Victoza's black box warning regarding MTC). The Court therefore cannot conclude that relator Dastous alleged the MTC Risk Conduct claims, and thus, he is not entitled to share in the proceeds of the government's settlement of those claims. See Rille, 803 F.3d at 372. As to the remaining relators, each of these relators alleged variations on the MTC Risk Conduct claims, including examples of such conduct that relator Kennedy did not allege. See, e.g., Ferrara's Compl. ¶¶ 88, 99 (alleging that Novo Nordisk "downplayed or minimized [Victoza's] black-box warning[] about thyroid cancer," including by "fail[ing] to distribute . . . []REMS[] information [regarding MTC risk] to

a large number of health care providers"); Myers's Compl. ¶ 159 (alleging that "Novo [Nordisk] [ ] encouraged its sales representatives to minimize the [Victoza] safety warnings and data by, among other things, . . . sandwiching the safety data between benefits of Victoza[] and other information"); Stepe's Compl. ¶ 71 (alleging that "Novo [Nordisk] direct[ed] its sales representatives . . . to say that 'MTC is the rarest form of cancer, 1 in 5 million Americans have it' and 'Victoza does not cause cancer in humans'"); Gratton's Compl. ¶¶ 93–94 (alleging that Novo Nordisk used certified diabetics educators to "'push back' on the FDA black box warning" by, for example, "explain[ing to physicians] how [the metabolic system of a laboratory rat] was substantially different from that of a human"). However, because the Court has determined that relator Kennedy alleged the material elements of the MTC Risk Conduct claims and equipped the government to investigate them, the first-to-file rule bars the remaining relators' claims based on this conduct.[12] See Hampton, 318 F.3d at 218 (barring a second-filed complaint alleging fraud that was "merely [a] variation[]" on the fraud already alleged by the first-filed complaint). Accordingly, the remaining relators are precluded by the first-to-file rule from recovering a portion of the MTC Risk Settlement Amount. See Dhillon, 617 F. App'x at 212 ("Only the first-filed [r]elator is entitled to a [r]elator's share award from a settlement.").

Thus, the only remaining issue for the Court to resolve as to the MTC Risk Settlement Amount is the objecting relators' argument that "general principles of equity require that [the objecting relators] . . . receive a portion of the settlement funds." Myers's Opp'n at 21 (capitalization removed). The Court must reject this argument, as well. Notably, the objecting

[12] Notably, the objecting relators do not dispute that their complaints are barred under the first-to-file rule. See, e.g., Myers's Opp'n at 19 (arguing that "[r]elator Dastous[] . . . first alleged the facts forming the basis of Novo[] [Nordisk's] scheme to minimize and mischaracterize Victoza's black box warning"); id. at 24 (arguing that "[s]trict application of the first-to-file bar . . . would be inappropriate" and that "equity demands" that relator Myers receive a share of the settlement proceeds).

relators have not cited, and the Court has not been able to locate, a single case applying an equitable exception to the first-to-file bar, and the Court is unaware of any authority that would permit it to recognize such an exception in this case. As the Ninth Circuit has recognized, "[§] 3730(b)(5)'s plain language unambiguously establishes a first-to-file bar, . . . [and] does not contain exceptions." United States ex rel. Lujan v. Hughes Aircraft Co., 243 F.3d 1181, 1187 (9th Cir. 2001) (internal citations omitted); see United States ex rel. Shea v. Cellco P'ship, 863 F.3d 923, 927 (D.C. Cir. 2017) ("The first-to-file bar [ ] ensures only one relator will share in the government's recovery." (emphasis added)). And, "[e]xceptions to clearly delineated statutes will be implied only where essential to prevent absurd results or consequences obviously at variance with the policy of the enactment as a whole." Lujan, 243 F.3d at 1187 (quoting United States v. Rutherford, 442 U.S. 544, 551–52 (1979)). No such circumstances are presented here. The objecting relators argue that, in light of their "substantial efforts and significant[] contribut[ions] . . . to . . . this qui tam action," Myers's Opp'n at 21, application of the first-to-file bar to their claims would undermine Congress's goal to "creat[e] a strong financial incentive for private citizens to guard against efforts to defraud the public fisc," id. at 23 (citation omitted). However, application of the first-to-file bar in this case simply reflects "congressional efforts to walk a fine line between encouraging whistle-blowing and discouraging opportunistic behavior." Hampton, 318 F.3d at 217. Thus, "an exception-free, first-to-file bar conforms with the dual purposes of the 1986 amendments: to promote incentives for whistle-blowing insiders and prevent opportunistic successive plaintiffs," see Lujan, 243 F.3d at 1187, and it is not for this Court to disturb "the [ ] balancing act of the FCA's qui tam provision," United States ex rel. Wilson v. Bristol-Myers Squibb, Inc., 750 F.3d 111, 117 (1st Cir. 2014).

The cases cited by the objecting relators do not provide support for their equitable argument. First, they cite the decision of another member of this Court for the proposition that "[d]istrict courts possess great discretion in making th[e] [relator share] award." Shea, 844 F. Supp. 2d at 81. However, this proposition addresses a court's discretion to determine the amount of an award a first-filed relator should receive, see id. (considering whether to grant a "[p]ercentage award[] above the statutory [minimum of fifteen percent]"), and does not recognize any such discretion applicable to a court's threshold determination of whether a relator is entitled to any award at all. Additionally, relator Stepe argues that "[t]he Court should [ ] follow [United States] v. Shire Regenerative Med[icine], Inc., . . . where the Court approved the [Department of Justice]'s proposal to allocate some portion of the relator's share to all six relators." Stepe's Opp'n at 16 (footnote omitted). However, that case is distinguishable, as well, because, in Shire, the court concluded that each of the six relators was a first-filer as to one or more of the various claims that formed the basis of the settlement at issue and awarded each relator only the portion of the settlement proceeds that was attributable to their claims. See Civ. Action Nos. 11-176-T-30MAP, 12-575-T-30TBM, 14-969-T-30TBM, 14-1055-T-30AAS, 16-268-T-30TBM, 16-303-T-30TBM, 2017 WL 6816615, at *6–7 (M.D. Fla. Nov. 20, 2017). Thus, neither of these cases supports the objecting relators' theory that a court may adopt an exception to the FCA's first-to-file bar.

In sum, the Court concludes that relator Kennedy's allegations equipped the government to investigate the MTC Risk Conduct claims, and thus, she is entitled to a portion of the MTC Risk Settlement Amount. The Court also concludes that relator Dastous is not entitled to share in the MTC Risk Settlement Amount and that relator Kennedy's allegations bar all remaining relators' claims to a portion of those proceeds. Thus, the Court will grant relator Kennedy's

request that she be awarded at least a fifteen percent share of the MTC Risk Settlement Amount. However, the Court must deny relator Kennedy's request that she be paid these funds "immediately," Kennedy's Mot. at 26, as the Court previously ordered that these funds "shall be held in the Court's registry pending the Court's adjudication of the . . . dispute amongst the relators over entitlement to a relator share . . . and until all appeals are exhausted (or the time for filing any notices of appeal has expired)," Order at 3 (June 1, 2018), ECF No. 99.[13] Accordingly, the Court will grant in part and deny in part relator Kennedy's motion that she receive a portion of the MTC Risk Settlement Amount.

B. The Off-Label Promotion Conduct

Relator Kennedy also asserts that she is the sole relator entitled to share in the Off-Label Promotion Settlement Amount. See Kennedy's Mot. at 22. As explained above, the Settlement Agreement asserts that Novo Nordisk "knowingly promoted the sale to and use of Victoza by adult patients who did not have [t]ype [2] diabetes, a use for which it was not approved as safe and effective by the FDA, that was not a medically accepted indication . . . , and not covered by [ ] [f]ederal [h]ealth [c]are [p]rograms." Settlement Agreement ¶ K(ii).

No relator disputes that relator Kennedy is the sole relator entitled to a share of the Off-Label Promotion Settlement Amount. See, e.g., Ferrara's Mem. at 4 ("The Ferrara [r]elators agree that [r]elator Kennedy is the first in time as to the off-label claims that were the subject of the Settlement [Agreement] in [p]aragraph ii."); Dastous's Not. at 3 (joining relator Kennedy's motion and the Ferrara relators' memorandum); Myers's Opp'n at 13 (disputing relator Kennedy's entitlement only as to the "scheme in which Novo [Nordisk] . . . attempted to

[13] The Court notes that relator Kennedy and the other relators did not object to the relief granted by the Court's June 1, 2018 Order. See, e.g., Relators' Joint Notice Regarding United States' Proposed Order for Deposit of Settlement Funds into the Registry of the Court at 1 (May 21, 2018), Kennedy, Civ. Action No. 13-1529.

undermine the FDA's REMS"); Stepe's Opp'n at 19 (same); Gratton's Opp'n at 9 (same). Consequently, the Court finds it appropriate to treat as conceded relator Kennedy's argument that she is the sole relator entitled to a portion of the Off-Label Promotion Settlement Amount. See Texas v. United States, 798 F.3d 1108, 1110 (D.C. Cir. 2015) ("[Local Rule 7(b)] is understood to mean that if a party files an opposition to a motion and therein addresses only some of the movant's arguments, the court may treat the unaddressed arguments as conceded."); see also Wash. All. of Tech. Workers v. U.S. Dep't of Homeland Sec., 892 F.3d 332, 345 (D.C. Cir. 2018) (observing that, "[i]n the context of non-dispositive motions, [this Circuit] ha[s] affirmed district court decisions that treated as conceded an issue left entirely unaddressed by [a party] in a timely filed response").

However, even if the relators did not concede this issue, the Court would nonetheless conclude that relator Kennedy is the sole relator entitled to a share of the Off-Label Promotion Settlement Amount. Relator Kennedy is entitled to a share of these proceeds because she alleges that Novo Nordisk promoted Victoza to "pre-diabetics," i.e., persons without type 2 diabetes, for diabetes "prevent[ion]," Kennedy's Compl. ¶¶ 103–05, and thus, she alleged the same fraud as the fraud underlying the Off-Label Promotion Conduct claims, see Settlement Agreement ¶ K(ii) (alleging that Novo Nordisk "knowingly promoted the sale to and use of Victoza by adult patients who did not have [t]ype [2] diabetes"). Moreover, four of the five remaining relators are not entitled to share in these proceeds because relator Kennedy's allegations regarding Novo Nordisk's marketing of Victoza to pre-diabetics, see Kennedy's Compl. ¶¶ 103–05, combined with her allegations that Novo Nordisk marketed Victoza for weight loss, see id. ¶¶ 1, 77, sufficed to put the government on notice of the off-label marketing schemes alleged in the subsequent Complaints, see Dastous's Compl. ¶ 3 (alleging that "Novo [Nordisk] has engaged in

an extensive, nationwide campaign to promote Victoza for . . . treatment of weight loss in . . . pre-diabetic populations"); Ferrara's Compl. ¶ 60 (alleging that "Novo [Nordisk] promoted [Victoza] for weight loss in non-diabetic patients"); Myers's Compl. ¶¶ 162–63 (alleging that Novo Nordisk "trained [sales representatives] to induce queries about off-label uses of Victoza[,]" including for weight loss); Stepe's Compl. ¶ 80 (alleging that "Novo [Nordisk] [ ] direct[ed] sales associates to sell Victoza . . . for non-diabetics . . . to prevent diabetes . . . because it assists with weight loss and . . . 'prevent[s]' weight gain"). And a fifth relator simply failed to allege an off-label promotion scheme for non-diabetic populations, and thus, has no right to share in the Off-Label Promotion Settlement Amount. See Gratton's Compl. ¶ 93 (alleging only that "Novo [Nordisk] would permit . . . [representatives] to speak off label about using Victoza with insulin").

Thus, the Court will also grant relator Kennedy's request that she be awarded at least fifteen percent of the Off-Label Promotion Settlement Amount. However, for the reason already explained, the Court must deny relator Kennedy's request that she be paid these funds "immediately." Kennedy's Mot. at 26. Accordingly, the Court will grant in part and deny in part relator Kennedy's motion for a share of the Off-Label Promotion Settlement Amount.

C. Relator Kennedy's Entitlement to the FDCA Settlement Amount

In her motion for an award of the Federal Settlement Amount and Named Plaintiff State Settlement Amount, relator Kennedy "reserve[d] the right to pursue through a separate motion payment of [a] relator's share from the FDCA settlement on 'alternate remedy' grounds under [§] 3730(c)(5)." Kennedy's Mot. at 12 n.8. However, the United States opposes relator Kennedy's claim to a share of the FDCA Settlement Amount in its response to her motion, see United States' Resp. at 15–18, and relator Kennedy and the Ferrara relators argue in favor of

relator Kennedy's claim in response to the United States' opposition, see generally Kennedy's Alternate Remedies Reply; Ferrara Relators' Alternate Remedies Reply.

Notwithstanding the parties' willingness to litigate relator Kennedy's claim to the FDCA Settlement Amount, the Court does not find it appropriate to resolve her claim at this time for two reasons. First, relator Kennedy has failed to present her claim to the Court in a motion as required by the Federal Rules of Civil Procedure. See Fed. R. Civ. P. 7(b)(1) ("A request for a court order must be made by motion."). Second, the Court lacks adequate briefing regarding an issue that is potentially dispositive of her claim, specifically, whether relator Kennedy waived her claim to the FDCA Settlement Amount by entering into the Settlement Agreement. See United States' Resp. at 16. Relator Kennedy argues that she "clearly preserved her rights to a share of the proceeds of the action, [ ] including any alternate remedies." Kennedy's Alternate Remedies Reply at 24. Alternatively, she argues that any waiver by her was "defective" because, "at the time she entered into the [ ] [S]ettlement [A]greement," she "had insufficient information to determine[] . . . whether the [government's] FDCA case . . . constituted an alternate remedy under the [FCA]," and thus, she "could not have made any knowing or intentional waiver of [her] claim." Id. at 22–23. The United States has not responded to either of these arguments. See generally United States' Resp. Moreover, relator Kennedy's argument that her waiver was defective relies on factual assertions that are not contained in the record before the Court or supported by affidavits or other evidence. See Kennedy's Alternate Remedies Reply at 22 (asserting without supporting proof that, prior to entering into the Settlement Agreement, she "was not advised as to the nature of the [g]overnment's claims, theory of the case, whether the matter was civil or criminal, or whether there was any monetary recovery or merely injunctive relief"). Thus, the Court finds the parties' current briefing on this claim inadequate and declines

to rule on it absent further briefing from the parties regarding the specific legal and factual arguments raised by relator Kennedy and, to the extent necessary, further development of the factual record. See Saunders v. District of Columbia, 711 F. Supp. 2d 42, 53, 55 (D.D.C. 2010) ("declin[ing] to make a ruling" on a potentially dispositive issue in an FCA case "[g]iven the inadequacy of the parties' briefing and the importance of th[e] issue").

III. CONCLUSION

For the foregoing reasons, the Court concludes that relator Kennedy is the sole relator entitled to at least a fifteen percent share of the Federal Settlement Amount and the portion of the Named Plaintiff State Settlement Amount paid to the states named as plaintiffs in her Complaint.[14] However, the Court declines to order that this share be immediately paid to relator Kennedy due to the Court's Order that this amount shall remain in the Court's registry until any appeals of this ruling have been exhausted or the time for noticing an appeal has expired. Additionally, the Court declines to rule on relator Kennedy's claim to a share of the FDCA Settlement Amount because it was not properly raised in a motion and has not been adequately briefed. Accordingly, the Court must grant in part and deny in part relator Kennedy's motion for an immediate award of the relator's share to which she is statutorily entitled.[15]

SO ORDERED this 11th day of September, 2019.

REGGIE B. WALTON
United States District Judge

[14] The relators collectively named thirty-one plaintiff states in their complaints, but relator Kennedy named only twenty-eight of those states as plaintiffs in her Complaint. See Named Pl. States' Mot. at 10 n.4; see also Kennedy's Compl. at 1–2. Thus, because relator Kennedy did not bring her suit on behalf of all the Named Plaintiff States, the Court cannot conclude that she is entitled to a fifteen-percent share of the entire Named Plaintiff State Settlement Amount and has included language limiting her award accordingly.

[15] The Court will contemporaneously issue an Order consistent with this Memorandum Opinion.