UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT TACOMA

UNITED STATES OF AMERICA, *et al.*, Plaintiffs, *Ex rel.*, JAMIE SIEGEL, M.D., Plaintiff-Relator, v. NOVO NORDISK, INC., Defendant.	CASE NO. C23-5459 BHS ORDER

THIS MATTER is before the Court on defendant Novo Nordisk's (NNI's) motion for summary judgment, Dkt. 386, and on plaintiff relator Jamie Siegel's and plaintiff intervenor Washington[1] State's motion for partial summary judgment, Dkt. 391.

[1] Plaintiffs filed single, a joint response to NNI's summary judgment motion, Dkt. 438, although Siegel alone asserts federal FCA claims.

The Court has described the factual context of this case in prior Orders, Dkts. 174 and 321, and in the interest of brevity will not recite the lengthy and complicated factual history reflected in the copious record.

Plaintiffs assert two federal claims against NNI: (1) a 31 U.S.C. § 3729(a)(1)(A) False Claims Act (FCA) claim, asserting that NNI presented or caused to be presented to the United States false or fraudulent claims for payment of NovoSeven prescriptions that were not reimbursable, because they were the result of NNI's promotion of NovoSeven for unapproved and dangerous high dose and prophylaxis "off label" uses, or the result of kickbacks paid to hemophilia physicians and patients to prescribe and seek NovoSeven (Count One); and (2) a 13 U.S.C § 3729(a)(1)(B) claim asserting that NNI knowingly made, or caused to be made, a false statement material to a false or fraudulent claim (Count Two).

Plaintiffs contend that NNI's conduct violated the federal, criminal, Anti-Kickback Statute (AKS), 42 U.S.C. § 1320a-7b(b)(2), which makes it illegal to knowingly and willfully offer or pay remuneration in cash or in kind in return for purchasing, ordering, or arranging for or recommending purchasing any good or service that is reimbursed by a federal health care program. They argue that the AKS violations make NNI's claims for reimbursement for NovoSeven false or fraudulent. Dkt. 270 at 22. The alleged FCA violations are limited to those that occurred in Washington State. Dkt. 321 at 28.

Plaintiffs assert two related state law claims: (1) a Washington Medicaid Fraud False Claims Act (WFCA, RCW § 74.66.005 *et seq*.) claim similarly asserting that NNI's

off label promotion and kickbacks made its claims for payment knowingly false or fraudulent (Count Thirty-One); and (2) a Washington Fraudulent Practices Act (WFPA, RCW § 74.09.210) claim asserting that through off label promotion and kickbacks, NNI made false statements, misrepresentations, and concealed material facts in order to induce Washington to pay for NovoSeven in an amount greater than that to which it was entitled (Count Thirty-Two). They argue that NNI's Washington Antikickback Statute (AKS) violations were a "fraudulent scheme or device." *Id*. at 21 (citing RCW 74.09.210(1)). They contend that NNI falsely represented that its claims for reimbursement complied with all applicable federal and state laws and regulations, including the AKS. Dkt. 270 at 114.

NNI seeks summary judgment on all claims, though most of its motion addresses only Count One.[2] It argues that "Patient A's" (the primary Washington Medicaid patient at issue) use of NovoSeven was medically appropriate and necessary. It contends there is no evidence[3] it promoted the off label use of NovoSeven to doctors or patients, and that because the use was medically necessary, the purported off label use was not "false." It contends there is no evidence of either scienter or materiality.

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[2] NNI's motion asserts only that the WFCA and WFPA state law claims fail for the same reasons that the federal FCA claims fail. Dkt. 386 at 38–39. Its response to Plaintiffs' summary judgment motion on Count Thirty-Two includes additional argument specific to that claim, discussed below, but that argument is not in its own summary judgment motion. Dkt. 427.

[3] Rule 56 and *Celotex* permit a defendant without the burden of proof to seek summary judgment by "pointing out the lack of evidence supporting plaintiff's case," thereby putting on the plaintiff the burden to identify evidence that, viewed in the light most favorable to her, would permit a jury to find in her favor. NNI's motion repeatedly asserts there is "no evidence," but it is also accompanied by some 1500 pages of exhibits, transcripts and reports. Dkts. 387, 387-1, and 389.

NNI also argues[4] that there is no evidence of "remuneration" paid to physicians or patients, that it intended to induce the use of NovoSeven, that it acted willfully, or that any claim resulted from any AKS violation. Dkt. 386.

Plaintiffs' response lays out in detail NNI's lengthy and national effort to increase the use and thus sales of NovoSeven, particularly in response to the FDA's approval of its only competitor, FEIBA, for prophylaxis. Dkt. 438 at 2–4. It emphasizes that the FDA denied NNI's applications for approval of high dose (270 mcg/kg) and prophylaxis use, but that NNI continued to promote such uses as part of its "Prophylaxis War Games," and its efforts to "convert" FEIBA users to NovoSeven. *Id.* at 2. Plaintiffs argue that NNI incentivized its biopharmaceutical sales managers (BSMs) to target such conversions because each conversion was worth at least $570,000 a year, Dkt. 438 at 3, and because it stood to lose $60 million per year if hemophilia patients used FEIBA for prophylaxis instead. *Id*. at 3, 6. Plaintiffs further argue that NNI paid influential physicians to speak and publish about high dose and prophylactic NovoSeven use, and that NNI viewed its patient support program, SevenSECURE, as its primary vehicle for obtaining profitable conversions. They argue that there is ample evidence that at least "one purpose" of these efforts was to induce increased use of NovoSeven. Plaintiffs argue that NNI's motion simply ignores this evidence. *Id.* at 27.

[4] NNI's motion also asserts that the FCA's *qui tam* provisions are unconstitutional and that its marketing is protected by the First Amendment. Dkt. 386 at 16 n.9 and 17. These contentions are rejected, notwithstanding Plaintiffs' decision not to respond to them.

Plaintiffs seeks partial summary judgment on its WFPA claim, Count Thirty- Two. They contend that through SevenSECURE, NNI gave benefits directly or indirectly to patients, including Patient A. They argue that NNI's kickbacks to patients violated the Washington AKS and was a "fraudulent scheme or device" for purposes of the WFPA. Dkt. 391.

NNI contends the WFPA does not apply to it because the Washington Medicaid payments for NovoSeven were made to pharmacies or hospitals, not NNI. It argues there is no support for the claim that a violation of the criminal Washington AKS can support civil liability under the WFPA, and that Plaintiffs have misrepresented or mischaracterized its SevenSECURE program. It contends there is no evidence of any payment of 'greater amount" than the provider was otherwise entitled, that it did not act with the required *mens rea*, and that there is no evidence that "one purpose" of the alleged kickbacks was to induce any patient to use NovoSeven. NNI also emphasizes that Washington knew about the SevenSECURE program and its alleged kickbacks for years but chose to reimburse for NovoSeven anyway. It contends that Washington's knowledge of the uses it paid for renders the claims not false.

The motions are well briefed. NNI's motion for summary judgment on the sole issue of the Beneficiary Inducement Statute is GRANTED. On the remaining issues, viewed in the light most favorable to the non-moving party, there is sufficient evidence and inference supporting Plaintiffs' claims, and NNI's defenses. These claims cannot be decided as a matter of law. NNI's motion for summary judgment is otherwise DENIED,

and Plaintiffs' motion for summary judgment is DENIED. The issues are addressed in turn.

I. DISCUSSION

A. Summary Judgment Standard

Summary judgment is proper if the pleadings, the discovery and disclosure materials on file, and any affidavits show that "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). In determining whether an issue of fact exists, the Court must view all evidence in the light most favorable to the nonmoving party and draw all reasonable inferences in that party's favor. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248–50 (1986); *Bagdadi v. Nazar*, 84 F.3d 1194, 1197 (9th Cir. 1996). A genuine issue of material fact exists where there is sufficient evidence for a reasonable factfinder to find for the nonmoving party. *Anderson*, 477 U.S. at 248.

The moving party bears the initial burden of showing that there is no evidence that supports an element essential to the nonmovant's claim. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). A moving defendant may meet this initial summary judgment burden by "pointing out to the district court that there is an absence of evidence to support the nonmoving party's case." *Celotex*, 477 U.S. at 325. Once the movant has met this burden, the nonmoving party must show that there is a genuine issue for trial. *Anderson*, 477 U.S. at 250.

The moving party is not required to negate the elements of the non-movant's case. *Lujan v. Nat'l Wildlife Fed'n*, 497 U.S. 871, 885 (1990). Rule 56's plain language

mandates the entry of summary judgment, after adequate time for discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial. In such a situation, there can be "no genuine issue as to any material fact," since a complete failure of proof concerning an essential element of the nonmoving party's case necessarily renders all other facts immaterial. The moving party is "entitled to a judgment as a matter of law" because the nonmoving party has failed to make a sufficient showing on an essential element of her case with respect to which she has the burden of proof. *Celotex*, 477 U.S. at 322–23 (citing *Anderson*, 477 U.S. at 250).

B. Federal FCA claims (Counts One and Two)

Plaintiffs' core contentions are that NNI improperly promoted NovoSeven for off label, unapproved and perhaps unsafe high dose and prophylaxis use, and that it violated the AKS by plying physicians and patients with remuneration—kickbacks—to induce them to prescribe and seek NovoSeven. As a result, they contend, NNI submitted or caused to be presented false claims to Medicaid in Washington (Count One). They similarly contend that NNI made false statements (about its compliance with various laws and regulations governing the submission of Medicaid claims) to obtain reimbursement for NovoSeven, making those claims false (Count Two). Dkt. 270.

There is a distinction, but Plaintiffs' claims share many of the same, disputed elements, and the evidence related to each is largely the same. NNI's motion, and this Order, addresses the bulk of the arguments and the evidence in connection with Count One.

1. NNI's Promotion of High Dose and Prophylaxis NovoSeven Use

NNI contends Plaintiffs' off label promotion claim fails because there is "no evidence" it promoted the off label use of NovoSeven, the claims submitted were not false because they were medically necessary, any "falsity" was not material, there is no evidence of scienter, and no evidence of causation. Dkt. 386 at 17. Plaintiffs assert there is ample evidence of each of these elements of the claim. Dkt. 438.

a. Off label promotion

NNI first contends that Plaintiffs have failed to uncover any evidence that it promoted NovoSeven off label to *anyone*. Dkt. 386 at 17. It argues there is no evidence it distributed scientific papers to any physician that prescribe NovoSeven to a Washington Medicaid patient.

Plaintiffs respond that there is evidence that NNI promoted off label NovoSeven uses to patients (including Patient A), providers, and other Inhibitor Summit attendees. Dkt. 438 at 5. They argue that NNI purchased and distributed "reprints" of scientific articles as part of its documented publication strategy. *Id.* at 9. They argue that NNI's publication strategy that "saturated the market" with off label messages that contained "misleading half truths"—representations that state the truth only so far as it goes, while omitting qualifying information." *Id.* at 17 (citing *Universal Health Servs., Inc. v. U.S. ex rel. Escobar,* 579 U.S. 176, 188–90 (2016)). They argue that NNI's failure to disclose that it funded and dictated the contents of purportedly independent scientifically accurate materials was a material half truth that would have affected the weight any provider gave the information.

On this threshold point, at this stage, the Court agrees with Plaintiffs that there is sufficient evidence that NNI promoted the off label, high dosage and prophylaxis use of NovoSeven.

b. Medically Accepted and Necessary

NNI next contends that under Washington Medicaid regulations, a prescription is reimbursable if it is for a medically accepted or necessary indication. Dkt. 386 at 19 (citing WAC §§ 182-530-2000(1)(a)(ii), 182-530-1050). It argues that a medically accepted indication means a use "supported by one or more citations included in any of the compendia of drug information," and that meeting the required compendial support is a "low bar" that it has met. *Id*. (citing *U.S. ex rel. Simpson v. Bayer Corp.*, 2014 WL 1418293, at *8 (D.N.J. Apr. 11, 2014) (off label theory of falsity failed where relator failed to show that no compendium supported the off label uses); *Dobson v. Sec'y of Health & Hum. Servs.*, 2022 WL 424813, at *10-11 (11th Cir. Feb. 11, 2022) (compendium entry is sufficient if it "tend[s] to show . . . the efficacy and safety" of an off label use)).

NNI argues that compendia support both the high dose and prophylaxis use of NovoSeven. It argues that despite the FDA's approval of NovoSeven's use for acute bleeds at 90 mcg/kg, high (or "single," 270 mcg/kg) dosage and prophylaxis uses were are not "off-label," because the label allows for "adjustments" in dosage and the FDA did not mandate a maximum dose. *Id*. at 19–21 (citing compendia).

It also argues that Washington determined whether a prescription is "medically necessary" (and thus reimbursable) under the so-called "hierarchy of evidence," outlined

in WAC §§ 182-530-1000(2)(e), 182-501-0165. *Id.* at 21. It argues that the two purported off label uses were medically necessary under this regulation, and thus not only were reimbursable, but in fact were required to be paid under Washington's Centers of Excellence Rule (COE), if the treating physician determined that the use was medically necessary. *Id*. at 22. It relies on the opinion testimony of its own expert, Dr. Manco-Johnson, that during the relevant period, experience and scholarship accepted the "off label" high dose and prophylaxis use of NovoSeven. *Id*. It also argues that, because the State's "failed to retain records," it is entitled to an adverse inference that Dr. Thompson concluded that the NovoSeven prescriptions of high does and prophylaxis were medically necessary. *Id*. And it argues that Patient A's physician, Dr. Louie, testified that his NovoSeven presubscriptions for such uses were the "optimal interventions" for him. *Id.*

NNI also argues there is no evidence that Washington ever determined that any Washington NovoSeven prescription was medically unnecessary, or that it denied any reimbursement claim on that basis, even though it referred Patient A's use to the Medicaid Fraud Control Unit in 2014. *Id*. at 23.

Plaintiffs respond that NNI's arguments about medical acceptance rely on compromised science it paid for, including its own expert, who relied in turn on the NNI-sponsored "Konkle Study" which the FDA declined to accept, other studies authored by NNI Key Opinion Leaders (KOLs), and the MASAC guidelines it manipulated. Dkt. 438 at 18. They persuasively argue that the resulting scientific debate is a question of fact precluding summary judgment.

Plaintiffs also argue that NNI cites to "compendia" not addressed by its experts, and that in any event "whether any particular use is 'supported by compendia' is a 'complex, case-by case inquiry'" Dkt. 438 at 18 (citing *U.S. ex rel. Brown v. Celgene Corp.*, No. CV 10–3165–GHK (SSx), 2014 WL 3605896, at *5 (C.D. Cal. July 10, 2014)). They contend that the cited compendia do not mention "prophylaxis." They argue that the compendia support "adjusting" the dosage to 180 mcg/kg, but that none of them support the single, high (270 mcg/kg) dose use NNI promoted. *Id.* at 19.

Finally, Plaintiffs argue that NNI has not established as matter of law that the off label NovoSeven use was medically necessary. They point out that NNI's argument depends in part on its own expert, Slen, and that NNI's reliance on the hierarchy of evidence is misplaced because that applies only where the drug in question requires "prior authorization" from Washington. *Id.* at 20 (citing HCA Chief Medical Officer Dr. Zerzan-Thul's Deposition, Dkt. 434-2 at 510) ("During the relevant time period, these drugs were not on prior authorization, so they were not reviewed prospectively."). Thus, they assert, the hierarchy of evidence is of no moment, and cannot be used to retroactively conclude as a matter of law that the off label use of NovoSeven was medically necessary. Plaintiffs emphasize that the Court should not accept on summary judgment NNI's expert Tarantino's challenged opinion, supported by NNI KOLs, that the NovoSeven use was medically appropriate or necessary, and that that is a question for the jury. *Id*. at 21.

The Court has determined that the missing records support an adverse inference instruction that those records would show that Washington accepted the claims as

medically necessary. Dkt. 480. However, it did not so conclude as a matter of law, and it cannot do so. The Court agrees that whether the off label use of NovoSeven was medically accepted or necessary is for a jury. Each of these arguments presents a question of fact precluding summary judgment on this issue.

c. Scienter

NNI argues that "What matters for an FCA case is whether the defendant *knew* the claim was false," and that there is no evidence it knew that the off label uses of NovoSeven rendered any claim false. Dkt. 386 at 24 (citing *U.S. ex rel. Schutte v. SuperValu Inc.*, 598 U.S. 739, 743 (2023) (emphasis added by NNI)). It argues that Plaintiffs have no evidence of the "critical element of scienter." *Id*.

Plaintiffs respond that "knowing" means acting "in reckless disregard of the truth or falsity of the information," and that "reckless disregard" "captures defendants who are conscious of a substantial and unjustifiable risk their claims are false but submit the claims anyway." Dkt. 438 at 21 (citing § 3729(b)(1)(A)(iii); *Schutte*, 598 U.S. at 751). They argue that NNI was on notice that the government viewed its promotion as false based on prior settlements[5] and the "Corporate Integrity Agreement" it executed to resolve similar claims in 2011. They argue that NNI's conduct was "knowing" under the FCA, and that its summary judgment motion on this point should be denied.

[5] Rule 408 generally prohibits the admission of settlement offers and negotiations for the purpose of disputing the validity of a claim or impeaching a witness. Here, Plaintiffs raise the prior settlements for a different purpose—to show NNI's knowledge of the FCA. Fed. R. Evid. 408(b).

The Court agrees. NNI's knowledge of the "falsity" of the claims is a question of fact for the jury.

d. Materiality

NNI argues that to be actionable under the FCA, a violation must be material, meaning it must have mattered to the government's decision to pay the claim. It argues that this test is rigorous and demanding Dkt. 386 at 24 (citing *Escobar*, 579 U.S. at 181, 194). It argues that under this test, if the government knows of the alleged violation and continues to pay anyway, that is "strong evidence" of immateriality. *Id*. at 25. NNI argues that there is no provision requiring that NovoSeven not be prescribed for the two off label uses at issue, and instead that under Washington law these uses must be reimbursed. *Id*.

NNI argues that Washington continued to pay for NovoSeven even when it knew, as early as 2007, that it was being used "off label." It argues that Washington has still never denied any claim for NovoSeven, despite frequently monitoring Patient A's use. NNI emphasizes that despite this scrutiny, Washington determined only that a specialty pharmacy had overbilled six times, all for FEIBA. It argues that continued payment despite knowledge of the supposed violation is "decisive." *Id.* at 25 (citing *U.S. ex rel. Kelly v. Serco, Inc*., 846 F.3d 325, 335 (9th Cir. 2017)). Relying on its expert Slen's report, NNI argues that Washington had numerous tools to "catch" improper off label NovoSeven use, and that it used two of these, but nevertheless kept paying, and indeed assisted Patient A's specialty pharmacy in submitting claims for off label NovoSeven use. *Id*. at 26. It argues that instead of rejecting the allegedly false claims, Washington

facilitated the payment of them, undermining as a matter of law Plaintiffs' current claim that NNI's off label promotion was material.

Plaintiffs respond that NNI's expert Jena testified that HCA relied on the MASAC guidelines that NNI had, without Washington's knowledge, manipulated, and used them to write regulations and make coverage determinations. They argue that had Washington known the truth, it could have scrutinized the claims more closely.

NNI's summary judgment motion on this point fails because the extent of Washington's knowledge of NNI's off label promotion, and thus the materiality of that promotion, are questions of fact for a jury.

e. Causation

Finally, NNI argues that because it did and does not itself submit claims to any health care program, Plaintiffs must provide evidence that it *caused* such submission. It argues there is "no evidence" of any causal connection between (1) any off label prescription and (2) NNI. Dkt. 386 at 27.

Plaintiffs respond that to prevail on the off label promotion claim, they must show that NNI's promotional activities caused physicians to write off label prescriptions which were presented to the government for reimbursement. Dkt. 438 at 22 (citing *U.S. ex rel. Penelow v. Janssen Prods., LP*, No. CV 12-7758 (ZNQ) (LHG), 2021 WL 6052425, at *9 (D.N.J. Dec. 21, 2021); *Celgene*, 226 F.Supp.3d at 1037).

They argue there is direct evidence that NNI's off label NovoSeven promotion—its marketing strategy—was a substantial factor in the submittal of claims for such prescriptions. *Id*. at 23 (citing Dkt. 433-1 at 203; Dkt. 414-2 at 26). There is other similar

evidence. *See* Dkt. 401 at 62 (January 14, 2010 email from NNI BSM Jerry Hanson to NNI's Steve Gunner regarding "losing" Patient A as a NovoSeven user, Dr. Louie, Dr. Mathew, prophylaxis use, and Hanson's effort to persuade them to use NovoSeven). *See also* Dkt. 434-1 at 77 (October 30, 2010 Hanson email to Gunner re his "coaching plan," and his review of his "last four calls with Dr. Louie" in furtherance of his "support of Dr. Louie's overall attitude of using [NovoSeven] as his main bypassing agent for his inhibitor patients especially his high use patient [Patient A]").

The Court agrees that a jury could reasonably conclude that NNI's conduct caused physicians to prescribe NovoSeven and that it was foreseeable that that would result in the submission of claims for payment for off label NovoSeven uses. *Id*. at 23. There is sufficient evidence to go to the jury that NNI viewed off label high dose and prophylaxis NovoSeven use as key to marketing its product, and there is also sufficient evidence it promoted that use. It is undisputed that Medicare or Medicaid paid for the vast majority of NovoSeven used, in Washington and elsewhere.

It would not be an "illogical leap[]," Dkt. 386 at 27, for a jury to conclude that NNI's efforts were successful and that they caused the submission and payment of claims for off label, high dosage and prophylaxis NovoSeven use.

2. Kickbacks to Physicians

NNI argues that Plaintiffs' AKS claim based on kickbacks to physicians fails for four reasons: (1) It paid no "remuneration" to any physician, (2) there is no evidence it intended to induce any recommendation or prescription, (3) there is no evidence it acted

willfully, and (4) Plaintiffs cannot establish that any claim resulted from any AKS violation. Dkt. 386 at 27–28.

a. Remuneration

The first argument depends on NNI's claim that it paid only fair market compensation to its KOLs and other physicians, and such compensation is not "remuneration" under the AKS. *Id*. (citing *United States v. Ctr. for Diagnostic Imaging, Inc.*, 787 F. Supp. 2d 1213, 1223 (W.D. Wash. 2011); *Bingham v. HCA, Inc.*, 783 F. App'x 868, 873-74 (11th Cir. 2019)). NNI's "fair market value" assertion relies on its expert, Janiga's "unrebutted" opinion that the NNI's payments were all at fair market value. *Id*. It also contends that nineteen of the transfers for value were within personal service safe harbor, 42 C.F.R. § 1001.952, as a matter of law. *Id.* at 29 (citing Exhibit 95, Dkt. 389 at 278–282).

Plaintiffs respond that under the AKS, fair market value is a defense, not an element of plaintiff's case. Dkt. 438 at 24 (citing *U.S. ex rel. Booker v. Pfizer*, 9 F.Supp.3d. 34, 52-3 (D. Mass 2014); *United States ex rel. Perri v. Novartis Phars. Corp.*, No. CV 15-6547, 2019 WL 6880006 at *13-14 (D.N.J Feb. 21, 2019)). They also argue that NNI's payments are not like those at issue in *Diagnostic Imaging*, which involved a discounted service agreement, or in the other cases upon which NNI relies, none of which involved payments to consulting physicians. Those cases could only be quantified by reference to fair market value. They argue that that is not true for compensation and benefits paid to consulting physicians, which includes travel to conferences, meals,

lodging, and opportunities for authorship. *Id*. at 24–25 (citing *Bingham*, 783 F. App'x at 873).

Plaintiffs also argue that NNI's own documents create factual disputes about whether any transfer to a physician exceeded fair market value, Janiga's report uses fair market value rates above those NNI used in its own 2012 policy, and NNI paid Dr. Kessler far more than even the highest tier rate in Janiga's report, under his 2005 consulting contract. And they argue that Janiga concedes he did not account for travel, lodging, or meals, even though HHS "OIG Guidance" states that these items can implicate the AKS if one purpose of the arrangement is to generate business. Dkt. 438 at 25 (citing 68 FR 23731 - 01, 2003 WL 2010428 at *13 (HHS 2003)).

Plaintiffs also contend that NNI has not established as a matter of law that its payments are within the AKS Safe harbor, 42 C.F.R. § 1001.952(d)(1)-(7). They argue that Janiga's report is also incomplete as it does not address pre-2012 payments or contracts, when, Plaintiffs assert, NNI was paying a premium for physicians with a greater "sphere of influence." *Id.* at 26. They argue that the actual relationship, not just the written contract terms, is the factual issue governing whether the payments were within the safe harbor.

The Court agrees that Janiga's report does not establish as a matter of law that the money NNI paid physicians in the relevant time period was not "remuneration," and for similar reasons agrees that the payments were not as a matter of law within the personal services safe harbor. Plaintiffs correctly contend there is evidence from which a jury could find that NNI compensated physicians in a manner that took into account the

volume or value of any referrals or business. *Id*. (citing 42 C.F.R. § 1001.952(v) (eff. Nov. 5, 1992)).

b. Inducement

NNI correctly contends that the AKS requires an intent to "induce" the purchase of a federally reimbursable health care product, and that it this context "induce" means "an intent to exercise influence over the reason or judgment of another." Dkt. 386 at 29 (citing 42 U.S.C. § 1320a-7b(b)(2), *Hanlester Net. v. Shalala*, 51 F.3d 1390, 1398 (9th Cir. 1995)). It argues there is no evidence that NNI transferred anything of value to the four Washington[6] prescribing physicians (Konkle, Kruse-Jarres, Recht, and Taylor) to induce prescriptions. It cites its own witnesses' testimony that the compensation was not tied to the volume or value of any referrals for prescriptions. *Id*. NNI argues that only Dr. Young was paid to attend and present at an Inhibitor Summit during the relative period, and he testified that NNI had no input on what he said at the Summit. And it argues that the AKS's "recommend" prong requires a recommendation to a particular patient, and that the AKS does not target "generalized promotion." *Id*. (citing *Celgene*, 226 F.Supp.3d. at 1056).

Plaintiffs reiterate that whether remuneration is intended to "induce" is determined by the One Purpose Rule: the statute is violated if "one purpose of the payment was to induce future referrals, even if the payments were also intended to compensate for

[6] The Court has twice ruled that Plaintiffs' national and other state law false claims act claims were not plausible, but it did not rule that evidence of NNI's conduct outside Washington was inadmissible to show that NovoSeven reimbursement claims in Washington were false. Dkts. 174 and 321.

professional services." Dkt. 438 at 27 (citing *United States v. Kats,* 871 F.2d 105, 108 (9th Cir. 1989) (quoting *United States v. Greber*, 760 F.2d 68, 69, 72 (3d Cir. 1985))). Plaintiffs argue that NNI's motion does not address the KOLs (including Dr. Kessler) who "manufactured" MASAC guidelines, and ignores Dr. Mathew, who it contends NNI "arranged to drive prophylaxis use by Patient A." *Id*. at 28. They argue NNI paid its KOLs based on their influence, and their 22 top KOLs were selected from Hemophilia Treatment Centers (HTCs) with large numbers of patients. *Id*. NNI argues that the selection of KOL numbers in part for their reputation and influence was not improper, but valid selection criteria. Dkt. 503 at 4. The resolution of this issue of fact is for the jury.

Plaintiffs argue that NNI's reliance on *Brown v. Celgene* for the proposition that the "recommendation prong" involves only recommendations that pertain to specific patients is misplaced. *Id*. *Celgene* relied on *U.S. ex rel. Kester v. Novartis Pharms. Corp.,* 23 F.Supp.3d 242 (S.D.N.Y. 2014), which held that the AKS does not require that kickback schemes succeed in generating new business for a violation to occur. *Id*. Plaintiffs argue that a "specific patient" requirement would be inconsistent with the FCA's language and purpose. Its language does not include ties to a specific plaintiff and reading such a requirement into the statue would hinder, not advance, the AKS's purpose of strengthening whistleblower actions based on kickbacks. *Id*. at 29 (citing H.R. REP. 95-393(II), 47, H.R. REP. 95-393, 47).

The Court agrees that the AKS does not require a plaintiff to prove that remuneration was paid to induce recommendations as to a particular patient. It also agrees that there is evidence of payments to physicians resulting in claims. Dkt. 438 at 30

(citing Dkt. 433-1 at 2) (Dr. Taylor's patients used about $400,000 of NovoSeven in 2012).

c. Willfulness

NNI argues that "willful" means an act undertaken with a "bad purpose," which in turn means the intentional violation of a known legal duty. Dkt. 386 at 30 (citing *Cheek v. United States*, 498 U.S. 192, 200-01 (1991). It argues there is no evidence it even suspected that its payments to physicians were unlawful.

Plaintiffs accurately assert that under the AKS, "willfully" means the defendant must act with knowledge of unlawful conduct. *United States ex rel. Hart v. McKesson Corp.*, 96 F.4th 145, 157 (2d Cir.), *cert. denied,* 145 S. Ct. 163 (2024). In the 9th Circuit, a defendant's conduct is willful if the defendant "knew or showed reckless disregard" for whether the conduct was prohibited by law. *Cassino v. Reichhold Chemicals, Inc.*, 817 F.2d 1338, 1348 (9th Cir. 1987). Plaintiffs point to the 2011 Corporate Integrity Agreement (CIA) NNI signed in connection with prior governmental assertions that its marketing was unlawful, and that it was in effect until 2016. At the very least, this is a sufficient basis for a jury to find a basis for "suspecting" that the conduct is unlawful. Therefore, this is a question of fact of the jury.

d. Claims and Payment Resulting from AKS Violations

NNI argues that the AKS requires "but-for" causation, requiring a plaintiff to prove that physician payments were the cause of the claim and payment. Dkt. 386 at 30 (citing *U.S. ex rel. Martin v. Hathaway*, 63 F.4th 1043, 1052 (6th Cir. 2023) (the "meaning of 'resulting from' is but-for causation"); *U.S. ex rel. Cairns v. D.S. Med.*

L.L.C., 42 F.4th 828, 834 (8th Cir. 2022) (the "phrase 'resulting from' . . . expresses 'a but-for causal relationship.'")). It argues that Plaintiffs' authority, *United States ex rel. Greenfield v. Medco Health Sols., Inc.*, has not been followed and is not persuasive. 880 F.3d 89, 97 (3d Cir. 2018) (the broad statutory text of FCA and AKS does not require plaintiff to show kickbacks directly influenced a patient's decision to use a particular medical provider).

NNI argues that the only physician who "received value" from NNI who prescribed NovoSeven in Washington, Konkle, testified that that compensation did not cause her to write a prescription for any patient. *Id*. at 31. It argues that Plaintiffs' only evidence on this point is its own expert, Fugh-Berman, and she establishes only that NNI's NovoSeven sales increased after the payments, but did not explore other possible causes for such increased sales. *Id*.

Plaintiffs do argue that they are not required to show but-for causation (or "direct influence") between the kickbacks and NovoSeven prescriptions. Dkt. 438 at 30 (citing *Greenfield* at 836). They also argue that the "resulting from" language did not apply before 2010. *Id*. at 31.

Neither a Washington District Court nor the Ninth Circuit has weighed in on the meaning of "resulting from" in this context. The Southern District of California held that a relator had sufficiently pled an AKS violation by plausibly alleging "a link" between kickbacks and claims for reimbursement, without determining whether the AKS requires but-for causation. *United States ex rel. Everest Principals, LLC v. Abbott Lab'ys, Inc.*, 622 F.Supp.3d 920, 933 (S.D. Cal. 2022) (acknowledging Circuit split).

It does not appear to this Court that a requirement for direct, but-for causation would be consistent with the purpose of the AKS, or the FCA. Absent a confession, it would be difficult to prove that the physician would not have prescribed the product but-for the payments. The Court need not so decide to deny NNI's motion on this point. Konkle's testimony may be regarded as self-serving and viewed in the light most favorable to Plaintiffs, the plain implication from the fact of increased sales—from NNI's well documented marketing strategy—is that the purpose of the payments was to influence physicians into prescribing its product. And while the Court does not necessarily agree that "NNI is liable under pre-2010 implied certification theory," it does conclude that but-for causation was not required prior to 2010. See *U.S. v. Regeneron Pharms., Inc.*, 128 F.4th 324 (1st Cir. 2025) ("nothing in the 2010 amendment . . . requires proof of but-for causation in a false-certification FCA case.").

NNI's motion for summary judgment on Plaintiffs' physician kickback FCA claim is **DENIED**.

3. Kickbacks to Patients

Plaintiffs allege that NNI paid benefits to Washington Medicaid patients to induce them to seek NovoSeven prescriptions. NNI argues that this claim fails for the same reasons that their "physician kickback" claim fails: It paid no remuneration to any Washington Medicaid patient through its SevenSECURE patient support program; there is no evidence it intended to induce, and none that it acted willfully. Dkt. 386 at 33. It argues that there is similarly no evidence that patient benefits resulted in any claim. It

argues that to the extent Plaintiffs' claims are based on violations of the Beneficiary Inducement Statute (BIS), they also fail.

The Court need not repeat its discussion above regarding intention to induce and willfulness, and the motion on the overlapping arguments is **DENIED**. The remaining, additional arguments are addressed in turn.

a. Remuneration

NNI's summary judgment motion relies heavily on its assertion that it effectively insulated itself from the SevenSECURE patient support program it founded, funded, and ran for two years, before hiring RxCrossroads to run it. It also relies on its own witnesses' testimony that NNI did not know whether a particular SevenSECURE participant was on Medicaid. Dkt. 386 at 9.

NNI argues that RxCrossroads was an "independent third party" that provided modest benefits to Hemophilia patients. Dkt. 386 at 33. It argues that RxCrossroads was the "sole arbiter" of benefit eligibility and benefit determinations. *Id*.

Plaintiffs respond that there is ample evidence NNI knew Patient A was a Washington Medicaid patient. Dkt. 438 at 31–32. They argue that NNI's claim that RxCrossroads was wholly "independent" is foreclosed by its prior, successful contention that RxCrossroads was the Functional Equivalent of an Employee (FEE), for purposes of the attorney-client privilege. *Id*. at 32 (citing *Macias v. Hunt & Henriques, LLP*, No. 8:24-CV-01496-DOC-DFM, 2024 WL 5185397, at *3 (C.D. Cal. Oct. 4, 2024) (quoting *Hamilton v. State Farm Fire & Cas. Co*., 270 F.3d 778, 782 (9th Cir. 2001)).

They also argue that the AKS applies to "whoever knowingly and willfully offers or pays any remuneration . . . directly or *indirectly*, overtly or covertly, in cash or in kind, to any person to induce such person." *Id*. at 33–34 (citing 42 U.S.C. §1320a-7b(2)) (emphasis added).

As an initial matter, the Court notes that NNI ran the program for two years, and there is evidence that it had "veto power" over at least some RxCrossroads benefits decisions. It does not agree that NNI's prior position on the attorney client privilege determines the issue of whether it had control over how its contractor spent its money. Joint defense agreements and discussions do not as a matter of law establish a principal-agent relationship. But a reasonable fact finder could conclude that RxCrossroads was hired to run NNI's program in an effort to increase sales of NovoSeven, by "targeting patients in underperforming sales territories with SevenSECURE." *See* Dkt. 398 at 12, 20.

Even absent the FEE issue, there is evidence that NNI viewed SevenSECURE as a vehicle for "converting" "target" patients to NovoSeven, that conversions were the best way to increase revenue, and that part of SevenSECURE's role was to provide benefits to these patients. RxCrossroads' performance under the contract was measured by its success in enrolling patients in SevenSECURE and referring patients to NNI BSMs. Dkt. 400 at 198. Other than distancing itself from RxCrossroads, NNI cannot dispute that it funded, even if indirectly, benefits that Patient A and his mother obtained through SevenSECURE. A jury could find that NNI would not have done these things if it did not intend to induce new prescriptions. It cannot be said as a matter of law that "not one

claim for reimbursement identified in this case that would not have occurred anyway." Dkt. 386 at 46 (citing *U.S. ex rel. Martin v. Hathaway*, 63 F.4th 1043, 1052 (6th Cir. 2023)).

NNI's summary judgment motion on this basis is **DENIED**.

b. Beneficiary Inducement Statute

Finally, Plaintiffs assert that the BIS prohibits

> [o]ffer[s] to or transfer[s of] remuneration to any individual eligible for [Medicare or Medicaid] that [the offeror] knows or should know is likely to influence such individual to order or receive from a particular provider, practitioner, or supplier any item or service for which payment may be made, in whole or in part, under [Medicare or Medicaid].

42 U.S.C. § 1320a-7a(a)(5) (part of the AKS). Remuneration "includ[es] … transfers of items or services for free or for other than fair market value," subject to certain exceptions. 42 U.S.C. § 1320a-7a(i)(6).

NNI argues that the BIS targets remuneration likely to influence the beneficiary's selection of only a "particular provider, practitioner, or supplier," not a particular manufacturer's *drug*. Dkt. 386 at 37 (citing HHS OIG, *Advisory Opinion No. 20-05* (Sept. 18, 2020) (the manufacturer's arrangement "would not implicate" the BIS—even though the proposed arrangement would influence a beneficiary to use the manufacturer's drugs).

Plaintiffs argue the OIG has "left open" the possibility that manufacturers could be liable if they "own or operate, directly or indirectly, pharmacies, pharmacy benefits management companies, or any other entities that file claims for payment under the Medicare or Medicaid programs." Dkt. 438 at 35 (citing 2002 Special Advisory Bulletin,

"Offering Gifts and Other Inducements to Beneficiaries," at 4 (available at https://oig.hhs.gov/fraud/docs/alertsandbulletins/sabgiftsandinducements.pdf)).

Plaintiffs argue RxCrossroads offers pharmacy services. The only supporting evidence they provide is in a footnote with a link to the RxCrossroads website. Dkt. 438 at 35 n.194. There is no evidence that SevenSECURE patients used RxCrossroads's pharmacy services. On this limited issue, NNI's motion for summary judgment is **GRANTED**.

4. FCA False Statement claim (Count Two)

Plaintiffs assert that NNI violated federal FCA, 31 U.S.C. § 3729(a)(1)(B), by "knowingly mak[ing], us[ing], or caus[ing] to be made or used, a false record or statement material to a false or fraudulent claim." Dkt. 270 at 88.

NNI argues that there is no false claim and no evidence of materiality, and that this claim fails as Count One fails. It argues that its supposedly false statements about compliance with the Corporate Integrity Agreement it executed in 2011 were not "part of" any claim for NovoSeven reimbursement. Dkt. 386 at 38.

Plaintiffs respond that the false statements claim involves far more than the CIA certifications; they are based on NNI's publishing strategy, its manipulation of the MASAC guidelines, its promotion of off label use and its kickbacks to physicians and patients all rendered its statements regarding claims for reimbursement for NovoSeven false. Dkt. 438 at 36. They argue that Washington began paying claims in 2012 based on the MASAC guidelines, making the fact that NNI did not disclose its role in the adoption

of those guidelines material, and caused it to pay for off label prophylaxis NovoSeven use.

NNI's motion for summary judgment on this claim is **DENIED**.

C. State law WFCA claim (Count Thirty-One)

NNI contends that Plaintiffs' state law WFCA claim fails for the same reasons that their federal FCA claims fail. Because the FCA claims do not fail, NNI's motion on this this state law claim is **DENIED**.

D. State law WFPA claims (Count Thirty-Two)

The Washington AKS (WAKS) criminally prohibits offering or paying "any remuneration (including any kickback, bribe, or rebate) . . . to any person to induce such person" to purchase or recommend "goods . . . for which payment may be made in whole or in part" under Medicaid. RCW 74.09.240(2); chapter 74.09 RCW. The WFPA provides a civil enforcement action against anyone who "on behalf of himself or herself or others, obtain[s] or attempt[s] to obtain" Medicaid benefits or payments by willful false statement, willful misrepresentation, or fraudulent scheme or device. RCW 74.09.210(1).

Plaintiffs seek partial summary judgment on their WFPA claim. Dkt. 391. They argue NNI violated the WAKS by providing kickbacks to inhibitor patients through SevenSECURE, and thus knowingly engaged in a fraudulent scheme or device to obtain Washington Medicaid payments under the WFPA. *Id.* at 20, 22. They again contend NNI cannot insulate itself from SevenSECURE because NNI previously asserted RxCrossroads was an FEE for privilege purposes. *Id.* at 27; Dkt. 404.

NNI does not dispute SevenSECURE provided benefits to hemophilia patients, but maintains RxCrossroads controlled and administered the program. Dkt. 427 at 6–7. NNI also argues the WFPA is nonetheless inapplicable to its conduct because the statute pertains only to benefits or payments obtained through false statements, the concealment of material facts, and fraudulent billing practices. Dkt. 427 at 20, 22. It argues the statute requires NNI to have received Medicaid reimbursements, which it claims only healthcare providers, not NNI, received. *Id.* at 20. It contends the rule of lenity requires any ambiguity in the WFPA and WAKS to be resolved in its favor. *Id.* at 24.

Finally, NNI asks the Court to grant summary judgment on the WFPA on its own motion, which merely argues "[t]he same analysis" it provides for the FCA and WFCA claims "dooms" the WFPA claim. Dkt. 427 at 37, Dkt. 386 at 38–39. It posits the WFPA does not hold "secondary actors like NNI" liable and provided only "administrative enforcement" prior to its amendment in 2012. *Id.* at 39.

Plaintiffs cite to SevenSECURE training slides with NNI's logo indicating the program provided "financial and supportive services," including medical expense and educational grants, to eligible hemophilia patients. Dkt. 399, Ex. 24 at 8, 11. NNI engaged RxCrossroads to "administer[] support to patients enrolled" in SevenSECURE, among other programs. Dkt. 400 at 193. The Statement of Work required, as a key performance indicator, RxCrossroads to offer 90% of program enrollees with an NNI representative contact every quarter. *Id.* at 198. Plaintiffs also point to NNI employee emails which mention SevenSECURE patient referrals, including emails to Washington NNI BSM Jerry Hanson discussing NovoSeven. Dkt. 453-1 at 7, 162.

NNI counters that RxCrossroads administered, implemented, and managed the program, citing deposition testimony in support. Dkt. 427 at 6. For example, RxCrossroads merely offered SevenSECURE enrollees "an opportunity to meet with a NovoNordisk representative," but "it was then up to the patient whether they decided to reach out or not." Dkt. 438, Leichter Dep., Ex. 150 at 64; Dkt. 427 at 9. And RxCrossroads employee Lawrence Hemming testified that it was RxCrossroads who made SevenSECURE benefits decisions for patients. Dkt. 438, Hemming Dep., Ex. 151 at 76. He stated he believed NNI "didn't want to be involved in the actual individual decisions." *Id.* at 77.

The parties provide and cite contradictory evidence on NNI's control over SevenSECURE, raising a genuine issue of material fact for trial. Because a reasonable trier of fact could conclude, in favor of NNI[7] that SevenSECURE was run independently by RxCrossroads, this issue is for the jury, not the Court on summary judgment, to decide.

NNI acknowledges that the arguments in its own WFPA summary judgment motion—that it was a "secondary actor" that did not receive Medicaid benefits and that the WFPA does not provide a civil cause of action—were already rejected by Judge Wyrick. Dkt. 386 at 39; Dkt. 174 at 26–27. Even if the Court can revisit issues Judge Wyrick already resolved, it should not and will not. Judge Wyrick's Order is thorough, well-reasoned, and in the Court's view, correct. *See* Dkt. 321 at 9.

[7] While NNI also moves for summary judgment on its WFPA claim, it does not base that motion on its alleged lack of control over the SevenSECURE program.

NNI's argument that the WFPA does not contemplate kickbacks to patients as a "fraudulent scheme or device" was not raised in its summary judgment motion, but rather in its response to Plaintiffs' summary judgment motion. Dkt. 427.

Plaintiffs' partial summary judgment motion, Dkt. 391, and NNI's summary judgment motion on Washington's WFPA claim, Dkt. 386, are **DENIED**.

II. ORDER

Therefore, it is hereby **ORDERED** that NNI's motion for summary judgment, Dkt. 386, is **GRANTED in part** solely on the issue of the Beneficiary Inducement Statute. The remaining issues cannot be decided as a matter of law. NNI's motion for summary judgment, Dkt. 386, is otherwise **DENIED**. Plaintiffs' motion for summary judgment, Dkt. 391, is **DENIED**.

Dated this 5th day of August, 2025.

BENJAMIN H. SETTLE
United States District Judge