UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

CIVIL ACTION NO. 11-12131-RWZ

UNITED STATES OF AMERICA
and THE STATE OF CALIFORNIA,
ex rel. KIMBERLY HERMAN, *et al.*

v.

COLOPLAST CORP., *et al.*

MEMORANDUM OF DECISION

August 17, 2018

ZOBEL, S.D.J.

Plaintiffs Kimberly Herman, Amy Lestage, and Kevin Roseff are current and former employees of a durable medical equipment manufacturer called Coloplast Corp. They bring this case as qui tam relators and allege in Counts IV, V, VI, and VII of their Third Amended Complaint that defendant Shield California Health Care Center, Inc. ("Shield"), conspired to and did submit improper reimbursement bills to the State of California in violation of the False Claims Act, 31 U.S.C. § 3729(a), and California's analogous state statute, Cal. Gov't Code §§ 12651(a).

Defendant has moved for summary judgment (Docket # 301) and to strike and exclude certain declarations and arguments submitted by plaintiffs in opposition thereto (Docket # 317).

I. Factual Background

Defendant provides medical equipment to beneficiaries of California's Medicare program (called "Medi-Cal") and then seeks reimbursement from that state and federally-funded initiative. This case centers on allegations that defendant's reimbursement claims overcharged the government[1] by means of an invoicing arrangement devised to circumvent Medi-Cal's billing regulations. Set forth below are the relevant facts which, when disputed, I view in the light most favorable to plaintiffs as the party opposing summary judgment. See O'Connor v. Steeves, 994 F.2d 905, 907 (1st Cir. 1993).

A. Medi-Cal's Upper Billing Limit Regulation

The California Department of Health Care Services (the "Department") administers Medi-Cal. In 2003, it filed an emergency regulation called the Upper Billing Limit ("UBL") to address "abusive billing conduct," including "the practice of obtaining steep discounts (whether legitimate or not) and then turning around and billing Medi-Cal at maximum reimbursement rates." See California Ass'n of Med. Prod. Suppliers v. Maxwell-Jolly, 131 Cal. Rptr. 3d 692, 714 (Cal. 2011) (upholding UBL against challenge brought by trade association (of which defendant in this case is a member)). In passing the UBL, the Department sought to close a "loophole in state law that did not effectively link reimbursement to the provider's purchase cost." Id. at 704 (quoting rulemaking record). In relevant part, the regulation achieves its purposes by limiting claims for reimbursement to a 100% markup of provider's "net purchase price" for an item. "Net

[1] The term "government" as used herein refers to the United States, the State of California, and their respective agencies and departments.

purchase price" is "defined as the actual cost to the provider to purchase the item, including any rebates, refunds, discounts or any other price reducing allowances, known by the provider at the time of billing the Medi-Cal program for the item, that reduces the item's invoice amount." Cal. Code Regs., tit. 22, § 51008.1(a)(2)(A). The UBL also requires that "[t]he net purchase price shall reflect price reductions guaranteed by any contract to be applied to the item(s) billed to the Medi-Cal program." Cal. Code Regs. tit. 22, § 51008.1(a)(2)(B). According to the UBL's Initial Statement of Reasons, "'net purchase price' is understood by the regulated community to be the amount actually paid for an item after all discounts or rebates have been taken." See Docket # 311-2 at 7.

"The [UBL] generated considerable public comment and opposition" when it was promulgated, "including comments by [defendant] and the trade association of which [defendant] is a member." Docket # 309 ¶ 3. How rebates and discounts should be treated for "net purchase price" calculations was among the topics discussed. For example, in response to an industry request that the UBL be amended to explicitly exclude "growth or volume discounts" from a product's net purchase price, the Department declined to change the rule and instead responded that the UBL "already excludes after the fact discounts." Docket # 309 ¶ 6. In response to other comments, Medi-Cal also clarified that "net purchase price includes rebates, discounts, credits and other price-reducing adjustments known to the providers at the time they bill for the item." Id. at Response to ¶ 6.

B. The Shield-Coloplast Scheme

In 2010, defendant's supplier agreement with medical supply manufacturer

Coloplast was expiring and the two companies negotiated a new contract. The agreement set forth the price of Coloplast's products in a series of tables attached to the contract. It also provided that, when Shield purchased enough products in a given three-month quarter, it would receive rebates to be paid by check no later than 60 days after the quarter's end. The rebates were structured into four tiers; the highest rebate ("Tier 4" for "Category A" products) equaled a 66% discount.

Plaintiff Herman, then President of U.S. Coloplast, and plaintiff Roseff, then Coloplast's Director of Distribution, were involved in the contract negotiation process. According to Roseff, the 2010 Shield-Coloplast agreement was "different" and "unusual." Docket # 311-4 at 6. The prices Coloplast was offering to Shield were "substantially higher than [for] any other customer," id. at 12-13, as were the "substantial discounts and rebates", id. at 6.[2] Mr. Roseff "had never seen a contract that had this type of incentive schedule attached to it," and the "double digit" rebates "jumped out" to him given their relationship to the high invoice prices. Id. at 12. Furthermore, evidence in the summary judgment record shows that Coloplast and defendant knew defendant would receive the rebates because they were based on sales figures defendant had previously met. Docket # 311-6 (December 2010 internal Coloplast email stating that new contract "increased [defendant's] invoice price significantly, but kept their net price the same"); Docket # 311-5 (deposition testimony

[2] Based on "similar supply agreements" that Coloplast had with other companies like Shield (so-called "master dealers") during the 2009-2012 time period, plaintiffs assert that "a comparison of the list prices for certain Coloplast products contained in [both the Shield and other companies'] agreements shows that Shield was paying an invoice price approximately 1.5 times to 2.5 times the invoice price received by other master dealers." Docket # 309 at 24 (referencing Docket # 314 (Belisle Declaration)). Similarly, "[a] comparison of the volume discounts ... shows that Shield was receiving after-the-fact volume discounts approximately ten times higher than the rebates received by other master dealers." Id.

of plaintiff Herman that Coloplast and defendant discussed a "purchase level commitment" during the 2010 contract negotiations which was "related to the rebates themselves" in that Coloplast "knew the level of business Shield was currently doing with the company" and defendant stated to Coloplast that they "intended to grow").

Like Roseff, plaintiff Herman, too, had concerns with the unusual contract and whether it was "compliant with what [she knew] about reimbursement [from Medi-Cal] and the way that it works." Docket # 311-5 at 11. She expressed these concerns during an in-person meeting with defendant and asked what it would do if Coloplast decided to abandon the agreement's structure. According to Herman, defendant told her it would not do business with Coloplast unless the agreement was set up in this fashion. Herman also remembers Shield telling her that the contract was arranged this way "because of issues related to how [defendant] bill[s] Medi-Cal." Id. at 16.

Herman believed that Shield was "gaming the system" by insisting on this type of contract, which required "pretty high prices and very high rebates." Id. at 17. She directed Roseff to work with Shield to add a disclaimer to all invoices stating, essentially, that the bills "may not reflect discounts, rebates, charge backs that may be recognized in the future." Docket # 311-4 at 5. Shield refused. In fact, when Roseff spoke with Shield's Purchasing Director Kyle Dunham about adding the language, Dunham said "if you do it, we don't have to do business with you." Id. at 11.[3]

[3] Defendant objects that this and other similar statements are merely hearsay. Summary judgment cannot be resisted by pointing to evidence that would ultimately be inadmissible at trial. Vazquez v. Lopez–Rosario, 134 F.3d 28, 33 (1st Cir.1998). However, it is sufficient at this stage to note that statements of high-ranking Shield employees like Director of Purchasing Kyle Dunham may be admissible if offered by plaintiffs as nonhearsay statements of an opposing party. See Fed. R. Evid. 801(d)(2)(D); see also Walden v. City of Providence, 495 F. Supp. 2d 245, 257 (D.R.I. 2007) (noting that "'technical rulings on the admissibility of evidence have no place in a summary judgment procedure,'" and that "'any doubts regarding the admissibility of any evidence should be resolved in favor of admissibility.'")

In the end, Coloplast relented and the high-price, high-rebate agreement went into effect in March 2010. From December 2010 through February 2014, defendant achieved the highest or second-highest level of rebates for every quarter. When Shield sought reimbursement from Medi-Cal for products it had purchased from Coloplast and then sold to patients, Shield calculated "net purchase price" using just the high invoice prices and never factored in the rebates. In 2014, Shield entered into another supplier agreement with Coloplast that again featured the high rebates, some as great as 70%.

Defendant admits that it "has never included off-invoice, after-the-fact rebates, such as those provided by Coloplast, to calculate the 'net purchase price,'" but denies that this practice transgresses the UBL or resulted in any false claims. See Docket # 302-2 ¶ 8. It maintains that the Coloplast rebates "are properly excluded from the 'net purchase price' calculation because these after-the-fact rebates are not known at the time of billing and do not reduce the invoiced amounts." Id. ¶ 7. It further believes that the invoice prices "reflect[] the actual purchase price," since Shield would pay Coloplast for the invoiced amount and only later, "[a]fter the end of each quarter, Coloplast calculated and paid to Shield any quarterly volume rebates earned by Shield." Id. ¶ 9. Shield argues that this method of calculating net purchase price "had been blessed by state and federal officials," and contends that its practice is "based on communications received in 2003 and 2004 from Medi-Cal officials and assurances it received from the

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(quoting 27A. Fed. Proc. § 62:708). The same may not be true for other evidence offered by plaintiffs, such as testimony by relator Herman about what other Coloplast employees told her about what unnamed Shield employees told them. See, e.g. Docket # 311-5 at 9 (Herman testifying that unidentified Shield employees told Coloplast employees Mr. Morell and Mr. McCandless that Shield was "perfectly fine with" increased invoice prices "because it goes into their calculation and how they bill to Medicaid"). That evidence has played no role in this summary judgment decision.

DOJ in resolving a prior qui tam lawsuit based on similar facts." Docket # 301-1 at 1.

C. The Donath Litigation

That prior lawsuit is United States ex. rel. Donath v. Whitestone Corp., No. SACV 07-0995 (C.D. Cal. 2007). There, qui tam relator Terry Donath alleged that his employer Whitestone Corp., a supplier of defendant's, and defendant struck a deal that employed an off-invoice, after-the-fact rebate program similar to that alleged in this case. The Donath litigation also involved other allegations, including that defendant violated the UBL in a more straightforward manner by simply not factoring into net purchase price discounts that actually appeared on its invoices (so-called "on-invoice discounts"). In addition, on April 19, 2010, Donath filed an amended complaint which included allegations that, beyond Whitestone, "Shield also entered into sham volume rebate agreements with ... most or all of its other suppliers," including Coloplast. Docket # 302-4 ¶ 148. The amended complaint alleged that defendant's invoice scheme "continues ... to this day," i.e. April 19, 2010. Id. ¶ 61.

The United States Department of Justice and the California Attorney General investigated Donath's allegations. Defendant cooperated and produced documents in response to a March 2008 investigative subpoena from the Office of Inspector General of the Department of Health and Human Services. The California Bureau of Medi-Cal Fraud and Elder Abuse then conducted an audit examining defendant's claims for four types of medical supplies submitted between March 1, 2003 and December 1, 2007. In due course, defendant resolved the Donath litigation in November 2011 by a $5 million settlement with the United States, California, and the relator. Docket # 121-1 at 165.

Important details about the Donath settlement are in dispute. In defense of its

billing practice, defendant contends that it "paid nothing ... for the off-invoice rebates/phony invoices allegations made by Donath," Docket # 302-2 ¶ 5; that the government "expressly declined to base any damages" on the alleged off-invoice scheme, Docket # 307-1 at 3; and that "the parties agreed" that the settlement was repayment for the on-invoice rebate omissions only, Docket # 306-1 ¶ 11. Defendant further contends that the government gave it "written assurances" to "protect it from future court and/or administrative actions seeking remedies for the off-invoice rebates allegations." Docket # 302-3 ¶ 11.

Plaintiffs offer a different view. According to the sworn affidavit of Siobhan Franklin, a Deputy Attorney General with the California Attorney General's Office who worked on the Donath investigation and the settlement, defendant's version of events is false. First, in response to defendant's claim that it "paid nothing" in the settlement relating to the phony invoicing allegation, Ms. Franklin states that "there was no such allocation of the settlement payment in the actual Settlement Agreement." Docket # 312 ¶ 12. She also notes that the "Covered Conduct" is specified as "Shield's overbilling the Medi-Cal program by charging more than twice the net purchase price of incontinence and other medical supplies in violation of [the UBL] during the period of March 1, 2003 through June 30, 2009." Id. Next, Ms. Franklin states that the "written assurances" described by Shield were merely unsigned, draft letters (one of which she herself wrote). She has no record of ever signing or sending a final version of such a letter and she points out that the draft letters did not give the assurances Shield claims. The letters "make[] no statement that Shield 'would not be sued again for the off-invoice allegations'" and instead both simply recite that the California DOJ and United States

Attorney General's Office did not have a "present intention" to bring or recommend a civil or administrative action with respect to any Donath claim that might be dismissed without prejudice under the proposed settlement. Docket # 312 ¶ 11; see Docket ## 301-20, 301-21 (unsigned draft letters). Finally, Ms. Franklin denies that Shield ever told her—during Donath or thereafter—that "in determining the net purchase price for medical supplies billed to Medi-Cal, Shield would [exclude] any large quarterly volume rebates paid by a manufacturer that may have been consistently achieved during the course of Shield's contract(s) with that manufacturer." Docket # 312 ¶ 13.

II. Legal Standards

A. Summary Judgment

Summary judgment is appropriate when the moving party "shows 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). "An issue is 'genuine' for purposes of summary judgment if 'the evidence is such that a reasonable jury could return a verdict for the nonmoving party,' and a 'material fact' is one which 'might affect the outcome of the suit under the governing law.'" Poulis-Minott v. Smith, 388 F.3d 354, 363 (1st Cir. 2004) (quoting Hayes v. Douglas Dynamics, Inc., 8 F.3d 88, 90 (1st Cir. 1993)). Summary judgment is improper where the non-movant "present[s] definite, competent evidence to rebut the motion." Advanced Flexible Circuits, Inc. v. GE Sensing & Inspection Techs. GmbH, 781 F.3d 510, 516 (1st Cir. 2015). In deciding this motion, I view disputed facts in the light most favorable to the non-moving party—here, the plaintiffs—and indulge all reasonable inferences in their favor. Thompson v. Cloud, 764 F.3d 82, 87 (1st Cir.

2014) (quoting O'Connor, 994 F.2d at 907).

B. False Claims Act

Under the False Claims Act, liability attaches to any person who "knowingly presents ... a false or fraudulent claim for payment or approval" to the government or "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(A)-(B). The Act's scienter requirement defines "knowing" and "knowingly" to mean that a person has "actual knowledge of the information," "acts in deliberate ignorance of the truth or falsity of the information," or "acts in reckless disregard of the truth or falsity of the information." Id. § 3729(b)(1)(A). "'[M]aterial' means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." Id. § 3729(b)(4).[4] Both the materiality and scienter requirements are "rigorous." Universal Health Servs., Inc. v. U.S. ex rel. Escobar, 136 S. Ct. 1989, 2002 (2016) ("Escobar II").

III. Discussion

Defendant argues that summary judgment should enter in its favor because plaintiffs will not be able to prove either the FCA's materiality or scienter requirements at trial. I examine each argument in turn.

A. Materiality

According to defendant, the conduct at issue here fails the materiality

[4] California's False Claims Act contains identical liability provisions. See Cal. Gov't Code § 12651(a)(1)-(2). It also defines "knowing," "knowingly," and "material" using the same language as the federal law. See id. § 12650(b).

requirement because "while DOJ and the State AG are well aware of [Shield's billing practice] and have actually known about the allegations that this practice is fraudulent since 2007, Medi-Cal has continued to pay Shield's claims, including those for Coloplast items, for the past ten years." Docket # 301-3 at 14. Moreover, Shield argues, "if the State AG suspected fraud in 2007 or at any time thereafter, it would have requested a Medi-Cal payment suspension, sought the recovery of overpayments resulting from the alleged scheme under the controlling federal Medicaid regulations, and/or taken other steps to stop the alleged fraud." Id.

According to plaintiffs, however, "Shield's argument rests in a disingenuous recitation of the Donath record." Docket # 310 at 11. Contrary to defendant's view of past events, plaintiffs contend that "the government did not have actual knowledge of Shield's UBL violations with Coloplast in 2007, nor did it have any reason to suspect that Shield would continue to submit false claims" after the settlement in Donath. Docket # 310 at 11-12. Plaintiffs argue that there is a genuine dispute of material fact as to whether defendant's omission of the Coloplast rebates from its net purchase price calculations was material to the government's decision to pay its reimbursement claims. In particular, they point to evidence supporting their interpretation of the UBL and argue that materiality becomes a jury question when a defendant has sought reimbursement from a government program in violation of important billing guidelines.[5]

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[5] In addition, plaintiffs rely upon the sworn declarations of Pansy Watson, current Chief of the Medical Supplies & Entreal Nutrition Benefits Branch in the Pharmacy Benefits Division with the California Department of Health Care Services. See Docket ## 313, 326. Ms. Watson declares that defendant's billing practices would be material to the Department's decision to pay the claims. Defendant has asked the court to strike the declaration because plaintiffs never disclosed Ms. Watson during fact discovery. It also argues that the testimony lacks foundation.

The court agrees that the declaration is improper because plaintiffs' failure to disclose Ms.

i. Escobar and the FCA's Materiality Standard

Under the Supreme Court's Escobar decision, the materiality vel non of an action to the government's payment decision is determined by "looking to the effect [of the action] on the likely or actual behavior of the [government]." Escobar II, 136 S. Ct. at 2002 (quoting 26 R. Lord, Williston on Contracts § 69:12, p. 549 (4th ed. 2003). The fundamental inquiry is "whether a piece of information is sufficiently important to influence the [government's] behavior ...." United States ex rel. Winkelman et al. v. CVS Caremark Corp., 827 F.3d 201, 211 (1st Cir. 2016). Materiality is "more likely to be found where the information at issue goes 'to the very essence of the bargain." United States ex rel. Escobar v. Universal Health Servs., Inc., 842 F.3d 103, 109 (1st Cir. 2016) ("Escobar III") (citing Escobar II, 136 S. Ct. at 2003 n.5).

"[C]ourts are to conduct a holistic approach to determining materiality in connection with a payment decision . . . ." Escobar III, 842 F.3d at 109. While "no factor [will be] necessarily dispositive," id., several considerations are relevant, including whether "the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated .... [o]r regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position." Escobar II, 136 S. Ct. at 2003-04.

ii. Materiality in This Case

Taking all reasonable inferences in favor of plaintiffs and viewing the disputed facts in the light most favorable to them, I am persuaded that a reasonable jury could

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Watson during discovery was neither justified nor harmless. See Fed. R. Civ. P. 26(a), 37(c)(1). It did not, therefore, consider Ms. Watson's testimony in ruling on defendant's summary judgment motion.

find that defendant's omission of the Coloplast rebates from its net purchase price calculations was material to the government's decision to pay defendant's reimbursement claims. Summary judgment is therefore inappropriate.

Defendant argues that the government's failure to suspend reimbursement payments, seek recovery of overpayment, or "take[] other steps to stop the alleged fraud" means that the practice of excluding the Coloplast rebates was immaterial to payment. Docket # 301-1 at 14. But a jury could see things differently. First, a jury could find that the government did seek recovery and take steps to stop the alleged scheme when, in Donath, it obtained a $5 million settlement payment from defendant for "overbilling the Medi-Cal program by charging more than twice the net purchase price of incontinence and other medical supplies in violation of [the UBL]." Docket # 312 ¶ 12. Though defendant protests that the settlement was related to Donath's "on-invoice" allegations only and that it received "cold comfort" letters condoning the exclusion of "off-invoice" rebates like those it received from Coloplast, those assertions are hotly disputed.

Second, a jury could find that the government's continued payment of defendant's post-Donath reimbursement claims has no bearing on whether the practice of excluding the Coloplast rebates was material to payment. A jury could find that the government did not have "actual knowledge" of defendant's billing practices because it reasonably assumed defendant would not persist in excluding discounts like the Coloplast rebates after settling Donath. Moreover, the record includes evidence from Attorney Franklin that, contrary to defendant's assertion, Shield never informed her it would continue to exclude such rebates from net purchase price when submitting

claims to Medi-Cal. Docket # 312 ¶ 13.

Were a jury to discredit Shield's view of these disputed facts, it could find materiality in this case. Noncompliance with the UBL is plainly material to the government's decision to pay a claim for Medi-Cal reimbursement. The billing regulation goes straight to the "essence of the bargain" between Medi-Cal and providers like defendant because it deals precisely with the amount that providers can bill. See Escobar III, 842 F.3d at 109. Moreover, this is not a case about "minor or insubstantial noncompliance" with collateral regulations. See Escobar II, 136 S. Ct. 1989, 2003 (2016) (holding that materiality cannot be predicated upon such de minimus conduct). Plaintiffs have submitted ample evidence for a jury to find that defendant was overcharging Medi-Cal by improperly omitting rebates when it reported the price it was paying for items in its claims for reimbursement. Specifically, there is evidence (recounted in greater detail above) that (i) the UBL at the very least requires rebates to be included in "net purchase price" calculations when they are both known and reduce an item's invoice amount; (ii) Coloplast and defendant entered into a supplier agreement under which Shield agreed to pay inflated invoice prices (1.5 to 2.5 times higher than other companies were paying) and received large rebates at the end of each quarter (ten times higher than the rebates received by other companies); (iii) defendant knew it would receive the rebates and in fact always did receive them; (iv) defendant purposefully structured the agreement and took actions during negotiations to prevent the rebates from appearing or being mentioned on its invoices, even though the rebates effectively reduced its actual costs by double-digit percentages; and (v) defendant never accounted for the rebates it received from Coloplast in its claims for

reimbursement. If credited by the jury, this evidence makes out a scheme that would be "sufficiently important to influence" the government's decision whether to pay defendant's reimbursement claims. Winkelman, 827 F.3d at 211; see United States v. DynCorp Int'l, LLC, 253 F. Supp. 3d 89, 103 (D.D.C. 2017) ("[I]t is common sense that the government would not pay claims if it knew that they were outrageously excessive"). Because the summary judgment record is replete with factual disputes on this issue, the motion fails as to materiality.

B. Scienter

Defendant also challenges plaintiffs' ability to prove scienter at trial. To win summary judgment on this ground, defendant must show that no reasonable jury could find that defendant omitted the Coloplast rebates from its net purchase calculations with either "actual knowledge," "deliberate ignorance," or "reckless disregard" of any requirement to include them. See 31 U.S.C. § 3729(b). "[I]t is unusual to grant summary judgment on scienter," given the fact-intensive nature of the inquiry. Massachusetts v. Mylan Labs., 608 F. Supp. 2d 127, 154 (D. Mass. 2008) (quoting S.E.C. v. Ficken, 546 F.3d 45, 51 (1st Cir.2008)).

Defendant contends that plaintiffs "fail to point to any evidence that Shield knew its practice of excluding future, off-invoice, after-the-fact rebates when calculating the net purchase price under the UBL was wrongful (false)." Docket # 318 at 2. It also argues that, under the framework of U.S. ex rel. Johnson v. Golden Gate Nat'l Senior Care, plaintiffs cannot establish scienter because (i) the UBL is "ambiguous" as to whether the Coloplast rebates should be included in net purchase price; (ii) defendant's interpretation that the rebates are properly excluded is "objectively reasonable"; and (iii)

"no formal guidance" from the government warned defendant that this interpretation was wrong. See Docket # 301-1 at 15; U.S. ex rel. Johnson v. Golden Gate Nat'l Senior Care, 223 F. Supp. 3d 882, 891 (D. Minn. 2016). Both arguments fail.

First, as detailed above, plaintiffs have proffered sufficient facts to support a jury finding that the 2010 Shield-Coloplast agreement was deliberately arranged to evade the UBL. On these facts, a jury could infer that defendant knew the regulation required rebates like those defendant received from Coloplast to be included when an item's "net purchase price" was calculated.

Second, the reasonableness of defendant's interpretation of the regulation and suggestions of government warnings away from that interpretation present mixed questions of fact and law best resolved by the jury when the material facts are in dispute. See U.S. ex rel. Westmoreland v. Amgen, Inc., 812 F. Supp. 2d 39, 71 (D. Mass. 2011); U.S. ex rel. Suter v. Nat'l Rehab Partners Inc., No. CV-03-015-S-BLW, 2009 WL 3151099, at *10 (D. Idaho Sept. 24, 2009) (denying summary judgment on scienter issue because reasonableness of defendant's interpretation of regulation was fact issue for jury); see also U.S. ex rel. Donegan v. Anesthesia Assocs. of Kansas City, PC, 833 F.3d 874, 879 (8th Cir. 2016) ("[S]ummary judgment is not proper on the issue of FCA scienter if a Relator ... produces sufficient evidence of government guidance that warn[ed] a regulated defendant away from an otherwise reasonable interpretation" of an ambiguous regulation.") (internal quotation marks omitted). That is the case here.

To begin, even assuming that the regulation is indeed ambiguous, a jury could nevertheless find that defendant's interpretation of the UBL is not objectively reasonable. Defendant reads the UBL as permitting exclusion of the Coloplast rebates

because (1) they are "off-invoice" (i.e. Coloplast did not list them on its bills to defendant); and (2) "after-the-fact" (i.e. the rebates were paid at the end of each quarter, presumably after defendant had submitted reimbursement claims to Medi-Cal). As support for its reading of "off-invoice," Shield points to the UBL's statement that "net purchase price ... includ[es] any rebates ... that reduce the item's invoice amount." (emphasis added). As support for an "after-the-fact" exception, Shield notes that "net purchase price ... includ[es] any rebate ... known by the provider at the time of billing the Medi-Cal program for the item ...." (emphasis added). A jury could find that neither of these interpretations is objectively reasonable.

The UBL says, first and foremost, that "net purchase price" is "the actual cost to the provider to purchase the item from the seller ...." Cal. Code Regs., tit. 22, § 51008.1(a)(2)(A)(emphasis added). Given that the Coloplast rebates, once received, effectively reduced defendant's purchase costs by as much as 70 percent for a given product, a jury could determine that it was not objectively reasonable to interpret the phrase "reduce the item's invoice amount" as allowing omission of large discounts simply because they did not appear on a bill. That is especially true given the UBL's purpose of curbing "the practice of obtaining steep discounts (whether legitimate or not) and then turning around and billing Medi-Cal at maximum reimbursement rates." See California Ass'n. of Med. Prod. Suppliers, 131 Cal. Rptr. 3d at 714.

Similarly, in the context of the Coloplast rebates at issue here, a jury could determine that it was not objectively reasonable to interpret the word "known" to mean that the rebates were excludable simply because they were paid later. Plaintiffs have adduced sufficient evidence that defendant did "know" it would receive the rebates even

before they were actually paid. Specifically, there is evidence that Coloplast "knew the level of business Shield was currently doing with the company" when the rebate thresholds were established and knew that defendant "intended to grow." See Docket # 311-5 (deposition testimony of plaintiff Herman). There is also evidence that the rebates "kept [defendant's] net price the same" despite the significantly increased invoice prices. See Docket # 311-6 (December 2010 internal Coloplast email). A jury crediting that evidence, especially in combination with the fact that defendant did achieve Tier 3 or Tier 4 rebates every quarter, could reasonably infer as alleged in plaintiffs' operative complaint that: (1) "Shield ... and Coloplast agreed on the 'true' price of an item," then "artificially set the invoice price at or above the amount necessary to allow Shield ... to bill Medi-Cal at the maximum reimbursement amount," and "then set up a 'rebate' ... which reduced the amount paid by Shield ... down to the true agreed-upon price," Docket # 121 ¶ 132; and (2) that "[t]he 'tiers' in the rebate agreement were pre-determined such that Shield ... would always qualify for a rebate. Thus, the rebates were known to Shield ...." Id. ¶ 149. If the jury found those facts and made those reasonable inferences, it could well determine that defendant's reading of "known" in the UBL rule to allow exclusion of the Coloplast rebates was not objectively reasonable.

Furthermore, turning to the third prong of the Johnson framework, a reasonable jury could find that the government warned defendant away from its interpretation. Defendant was aware that California regulators drafting the UBL believed that "'net purchase price' is understood by the regulated community to be the amount actually paid for an item after all discounts and rebates have been taken." Docket # 311-1 at 4. A jury could find that statement was sufficient warning that defendant's self-serving

reading of the terms like “reduce the item’s invoice amount” and “known” contravened the regulation. Furthermore, defendant was also aware that Medi-Cal rejected industry representatives’ request to amend the UBL “to exclude ‘after the fact discounts’ dependent on ... aggregate volume of purchase from the seller from the net purchase price.” Docket # 311-10 at 1. Rather than amending the UBL, Medi-Cal responded by clarifying that it “already excluded discounts not known to the provider at the time of billing.” Id. (emphasis added). A jury could find that this statement warned defendants that structuring its contracts to pay high invoice prices up front and regularly receive large rebates each quarter was not license to omit those rebates from its net purchase price calculations where, as here, defendants consistently achieved those rebates and reaped large discounts they never passed on to Medi-Cal.

Stepping outside the Johnson framework, the foregoing discussion makes plain that a jury could find defendant submitted reimbursement claims to Medi-Cal with at least “reckless disregard” for whether the UBL required that the bills incorporate the Coloplast rebates. In addition to these facts is the fact that defendant paid $5 million to settle allegations of overcharging in Donath. See Docket # 312 ¶ 12. While the FCA's knowledge requirement is strictly enforced to avoid “penalizing a private party for violating a rule without first providing adequate notice of the substance of the rule,” Satellite Broad. Co. v. FCC, 824 F.2d 1, 3 (D.C. Cir. 1987), a reasonable jury could find that this is not such a case. For all these reasons, defendant’s motion for summary judgment on this ground is denied.

IV. Conclusion

Defendant's Motion for Summary Judgment (Docket # 301) is denied. Its Motion to Strike (Docket # 317) is denied as moot consistent with the court's rulings herein.

August 17, 2018

DATE

/s/Rya W. Zobel

RYA W. ZOBEL
SENIOR UNITED STATES DISTRICT JUDGE